

# Episurf Medical



*First Episealer® Talus surgery in France, performed by Prof. Jean Brilhault at the Hôpital Trousseau in Tours, France. Assisted by Prof. Niek van Diek.*

**Annual Report 2020**

## Content

|                                             |    |
|---------------------------------------------|----|
| This is Episurf Medical .....               | 3  |
| Highlights of 2020 .....                    | 4  |
| Statement from the CEO .....                | 5  |
| History .....                               | 6  |
| A much-needed method .....                  | 7  |
| Episurf Medical's technology .....          | 8  |
| Business idea, goals and strategy .....     | 9  |
| Strategy .....                              | 10 |
| Business model .....                        | 11 |
| Our Clinical Advisory Board .....           | 12 |
| Epioscopy® .....                            | 13 |
| Market overview .....                       | 14 |
| Episurf Medical's product portfolio .....   | 19 |
| Clinical evidence .....                     | 24 |
| Organisation and employees .....            | 28 |
| Share capital and ownership structure ..... | 29 |
| Administration report .....                 | 32 |
| Corporate governance report .....           | 43 |
| Internal control .....                      | 50 |
| Board of Directors .....                    | 51 |
| Executive management .....                  | 53 |
| Financial statements, contents .....        | 55 |
| Statement of assurance .....                | 85 |
| Auditor's report .....                      | 86 |
| Definitions .....                           | 89 |
| Glossary .....                              | 90 |
| Annual General Meeting .....                | 92 |

# This is Episurf Medical

– a unique solution for every patient

**EPISURF WAS FOUNDED IN 2009** on a commitment to offer people with painful joint injuries a more active and healthy life through customised treatment alternatives. We put the patient in the centre of the design of implants and surgical instruments. By combining advanced 3D imaging technology with the latest manufacturing technologies, we are able to adapt not only each implant to the patient's injury and anatomy, but also the surgical instruments used. In this way, we can ensure that each patient receives treatment that is perfectly suited to his or her anatomy and, thus, ensure a faster, more secure, and better patient-specific treatment for a more active and healthy life.



## A proprietary web-based IT platform for individualised design and surgical pre-planning

Episurf Medical's scalable  $\mu$ iFidelity® system has been developed for damage assessment, surgical pre-planning and cost-effective patient customisation of implants and associated surgical instruments. In a first step, the company's main focus has been on early stage arthritic changes in the knee joint. This is now followed by lesions in the second joint, the ankle.

## Individualised implants with a focus on early stages of arthritis

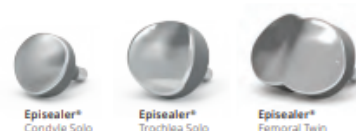
### Episurf Medical has three types of knee implants on the market

» Episealer® Condyle Solo for the treatment of

localised cartilage and underlying bone defects on the femoral condyles of the knee joint.

» Episealer® Trochlea Solo for the treatment of localised cartilage and underlying bone defects in the area behind the patella (the trochlea area).

» Episealer® Femoral Twin for the treatment of elongated localised cartilage and underlying bone defects both on the femoral condyles and in the trochlea area of the knee joint.



### Episurf Medical has one implant for the ankle on the market

» Episealer® Talus intended for osteochondral lesions of the talar dome of the ankle joint.

## Patient-specific surgical instruments

Every implant is delivered with our individualised surgical drill guide Epiguide® and a set of associated surgical instrument. Further, for the ankle Episurf Medical offers an individualised sawguide, Talus Osteotomy Guide. It is intended to help the surgeon to find the correct position and depth when performing an osteotomy of the medial malleolus for access to the talar dome of the ankle joint.



## Patents and patent applications

The generation of new intellectual property and the ongoing maintenance of current IP is of paramount importance for Episurf Medical to ensure that Episurf Medical's proprietary, existing technologies and future innovations are well protected. In total Episurf Medical has approximately 200 patents and patent applications worldwide, distributed over 30 patent families.

» The first Episealer® surgery in a human was performed in December 2012. At the end of 2020, a total of 825 surgeries had been performed.

» Episurf Medical's head office is located in Stockholm and the company has an in-house sales organisation in Europe.

» The share (EPIS B) has been listed on Nasdaq Stockholm since June 2014.

| Key ratios                       | 2020 | 2019 | 2018 | 2017 | 2016 |
|----------------------------------|------|------|------|------|------|
| Number of surgeries performed    | 227  | 192  | 147  | 103  | 86   |
| Number of new CE-marked products | 2    | 2    | 1    | -    | 1    |
| Number of new patents            | 15   | 13   | 13   | 6    | 11   |
| Number of countries (surgeries)  | 13   | 7    | 8    | 9    | 7    |

## Highlights of 2020



- » Episurf Medical conducted a directed share issue and fully guaranteed rights issue of in total SEK 140m prior to transaction costs
- » Episurf Medical received CE mark for Episealer® Talus and Talus Osteotomy Guide
- » Episurf Medical updated on AI-based production process
- » Episurf Medical reached milestone of 700 implants
- » Episurf Medical announced that the first surgery in Italy has been scheduled
- » Episealer® was presented at a sports medicine meeting in Germany
- » Clinical data for Episealer® were presented at orthopaedic congress in The United Kingdom
- » Important European patent approval received for Episurf Medical within 3D visualisation
- » Episurf Medical announced positive results from a clinical study with follow-up of the 30 first Swedish patients
- » Episurf Medical announced progress for European sites in the US clinical trial, the EPIC-Knee study
- » Episurf Medical announced positive results from the first comparative Episealer® study
- » US patent approvals for Episurf Medical
- » Episealer® Talus was registered for sale in Italy and Spain



- » Episurf Medical announced that results from Episealer Knee® multicenter study have been submitted
- » Episurf Medical has received patent approvals in Europe, Korea, Japan
- » Episurf Medical announced that the first surgery in the Asia-Pacific region has been scheduled
- » Episurf Medical announced that enrolment of patients has been initiated in North America and Europe in Episurf Medical's IDE clinical trial



- » Results from Swedish multi-centre clinical trial with follow-up of 30 Episealer® patients was accepted for scientific publication
- » Results from European multicenter study with follow-up of 80 Episealer® patients was accepted for scientific publication
- » Episurf Medical provided long-term market share targets for the Episealer® knee technology in the initially prioritised markets
- » Episurf Medical became an approved supplier to BMI Healthcare, the largest hospital provider in the UK
- » Episurf Medical received patent approval in Europe
- » Episealer® implants were approved for sale in France
- » Episealer® surgery in France and Poland was scheduled, which constitute new markets for Episurf
- » First surgery was performed in Episurf Medical's IDE study for the Episealer® Knee implant
- » Episurf Medical reached a milestone of 800 approved implants



- » Episurf Medical carried out a directed share issue and raised SEK 66m
- » Episurf Medical entered into licensing agreement of SEK 1.5m for µFidelity® software platform
- » Episurf Medical entered into a distribution agreement for France and additional markets in Asia
- » Episurf Medical entered into an advisory agreement with Prof. Doctor João Espregueira-Mendes regarding establishment of the Episealer® knee technology in India and Portugal
- » Data showing high implant survival rate for Episealer® were accepted for publication
- » The first Episealer® surgery was performed in the US, Asia and Scotland
- » First Episealer® Talus surgery in Scandinavia performed
- » Episurf Medical reached milestone of 900 approved implants

### Significant events after the end of the financial year

- » Episurf Medical announced its intention to file a 510(k) application in the US for an Episealer® Patellofemoral System
- » First Episealer® Talus surgery in the Asia-Pacific region performed
- » New patents approved in Hong Kong and US for Episurf Medical
- » Episurf Medical entered into distribution agreement for Australia and New Zealand
- » Episealer®: Clinical results with 5-years' follow-up data will be presented at the 3rd World Arthroplasty Congress
- » Clinical results for Episealer® were accepted for presentation at the 19<sup>th</sup> ESSKA congress
- » Episurf Medical provided COVID-19 related update ahead of an investor conference

## Statement from the CEO

Dear Shareholder,

This annual report marks the end of 2020. Despite the challenges created by the pandemic, it was a successful year for Episurf Medical. I would like to revisit a few of the key accomplishments from 2020 in this CEO statement. If you have an interest in Episurf, I will encourage you to listen to people other than myself; namely, the customers and patients who have shared their stories with us during the year. Our quarterly newsletter (subscribe through our website) is constantly sharing interviews with customers and patients. During our capital markets day (available on YouTube) in September 2020, three orthopaedic surgeons explained the rationale behind their interest in the Episealer®. On the same occasion, we also listened to a UK patient who shared his story leading up to surgery with an Episealer®. At the Bristol Oxford Knee meeting in November, three orthopaedic surgeons presented data from the largest European multicenter study on the Episealer® (also available on YouTube). These are just a few of many examples of what I believe is the best illustration of the capabilities of the Episealer® technology, and I encourage anyone interested in Episurf to look this up.



During 2020, among several things, we announced the following;

- We announced that a manuscript with the title *"Patient specific metal implants for focal chondral and osteochondral lesions in the knee – Excellent clinical results at 2 years"* from a European multicentre study with 24 months' follow-up of 80 Episealer® Knee implant patients had been accepted for publication in the scientific journal Knee Surgery, Sports Traumatology, Arthroscopy (KSSTA).
- We announced that post-market surveillance survival data (*Patient-specific implants for focal cartilage lesions in the knee: implant survivorship analysis up to seven years post-implantation*, by L. Ryd, K. Flodström and M. T. Manley) for the Episealer® Knee implant had been accepted for scientific publication in the peer-reviewed journal Surgical Technology International. The data showed a cumulative survival rate of >96% over 7 years.
- We announced promising results from the study with the title *"X-ray fluoroscopic analysis of knee joint kinematic in open and closed chain activities in patients with Episealer Knee implants"* performed at Charité University Hospital, Berlin. Preliminary results showed good patient satisfaction and good knee function.
- We announced that results from a clinical study with follow-up of the 30 first Episealer® patients from nine Swedish clinics had been accepted for publication in the scientific journal Cartilage. The study reported on good implant safety and significantly improved patient-reported outcome scores. In total, 30 patients were included in the study and the average follow-up time was 55 months.
- We announced that we had been informed about positive results in a clinical study with follow-up at 5-7 years of the 10 first patients to receive an Episealer® Knee implant.
- We announced that the first surgeries in the US clinical trial (the EPIC-Knee study) had been performed.
- We announced the first Episealer® surgeries in Asia.
- We announced the regulatory clearance and distributor arrangements in several global regions.
- We announced the launch of an AI-based in-house developed segmentation software, used in the production of the Episealer® knee implants.
- We announced the CE-approval of the Episealer® Talus and Osteotomy Guide – a revolutionary technology for the treatment of osteochondral lesions on the talar dome of the ankle joint.
- We announced the execution of two financing rounds, totaling SEK 207 million, including several Swedish pension funds and other renowned institutions among the investors.

During 2021, we will work hard to continue to deliver on our strategy, and we believe the road ahead is reasonably straightforward. Key priorities include:

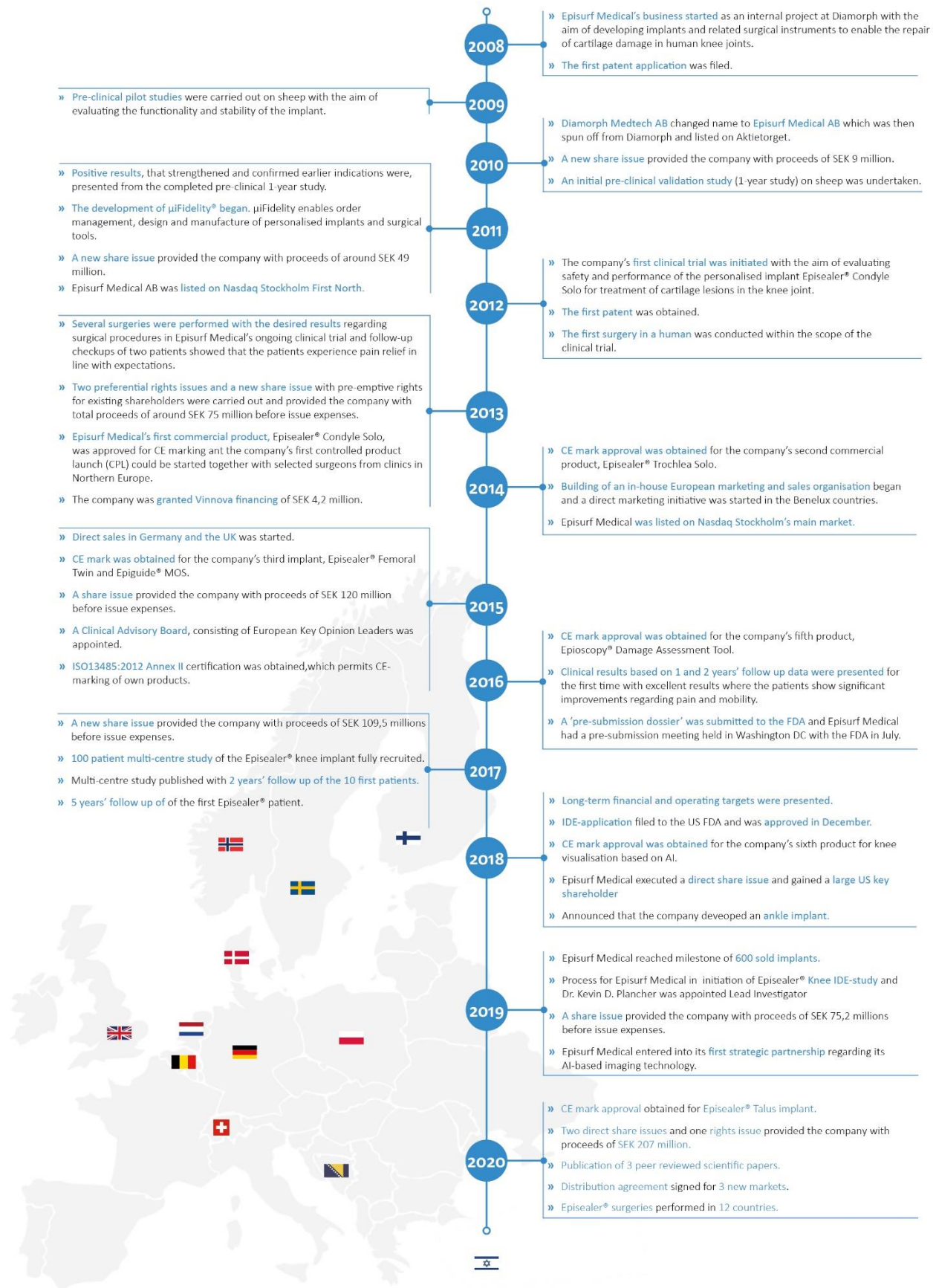
- Generating additional clinical evidence supporting the Episealer® technology.
- Making solid progress on the US IDE clinical trial (the EPIC-Knee study).
- Secure a continued successful roll-out of the Episealer® implant technologies in several global regions.
- Complete a 501(k)-submission for the Episealer® Patellofemoral System.

Following the substantial progress in 2020, the Episurf team remains highly optimistic about our future prospects. The reality is that several patients whom the orthopaedic industry was unable to help now report solid results over several years. That is the essence of it all. The rest is strategy execution, we believe.

Stockholm, March 2021

Pål Ryfors, CEO

# History



## A much-needed method

Episurf Medical was founded on a commitment to answering the question: is it possible to develop a new solution for treating pre-arthritis cartilage damage in a way that relieves pain and restores function?

**THE GOAL WAS TO FIND A SOLUTION** that was suitable for the younger, more active generation and would not limit the options for further treatments later in life. Against this background, Episurf Medical began its journey in 2008 as an internal project within Diamorph AB. The so-called “implant project” started with a focus on developing a solution to treat painful cartilage damage in human joints at an early stage, with the shortest possible rehab time. A number of patient-critical requirements were identified during the first pre-clinical trials that were carried out together with researchers at Karolinska University Hospital, the Royal Institute of Technology (KTH) and the Swedish University of Agricultural Sciences (SLU). Here, different implant designs, implant materials and surgical techniques were tested.



It soon became clear that to succeed in using implants with the aim of recreating a perfect, weight-bearing joint surface that is restored to its original function, a patient-specific design and rigorous surgical precision was required. New design criteria was formulated in which the focus was shifted from developing new implant materials to cost-effectively designing and manufacturing customised implants and precision surgical instruments to achieve long implant longevity, ensure replacement of only the damaged cartilage surface and preserve the healthy joint tissue.

Since 2010 Episurf Medical has worked with development of an IT platform called  $\mu$ iFidelity®. The platform supports the design and manufacture of implants that are uniquely tailored to each individual patient, which represents a new era in the field of orthopaedics where “one size fits all” implants is the general rule today. Concepts and knowledge have been gathered among other things from the dental industry, where customised dental crowns are now the industry standard. Episurf Medical aims to revolutionise orthopaedics by offering patient-specific implants and surgical tools for treatment of painful joint damage.

Episurf Medical’s first implant products, Episealer® Condyle Solo, Episealer® Trochlea Solo and Episealer® Femoral Twin received CE mark approval in 2013, 2014 and 2015, respectively. The Episealer® implants are the world’s first patient-specific resurfacing implants for treatment of cartilage damage in the knee joint. This is just the beginning of what Episurf Medical can do with its technology. After that the company has received CE-mark approval for Epioscopy® Damage Assessment Tool, Episealer® Talus and Talus Osteotomy Guide.

## Episurf Medical's technology

### *From MRI to customised implant and surgical tools*

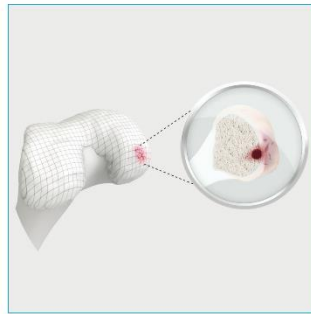
#### **The µiFidelity® system**

Episurf Medical's µiFidelity® system is a proprietary web platform for order management, communication, patient-specific design and surgical pre-planning. µiFidelity® is, as far as the company is aware, first in the world to deliver 3D visualisation support for patient-specific assessment of cartilage damage in joints and precision engineered production of patient-specific resurfacing implants and surgical tools.

**The figures below show the flow of Episealer® knee implants, but the same technology is used for Episealer® Talus**



- 1 The treating physician uploads MRI data to the µiFidelity® system.
- 2 The joint damage is localised and visualised with the help of the software.
- 3 Episurf Medical's medical experts assess the treatment alternatives for the patient.
- 4 The treating physician decides on the best treatment method.



- 5 A plan for optimal positioning of the implant is created in 2D and 3D at the same time that clinical considerations are taken into account.
- 6 An implant is designed to specifically match the position of the damage and the patient's unique anatomy.



- 7 Patient-specific surgical instruments are designed.
- 8 The patient-specific drawings of the implant and surgical instruments are transferred digitally to Episurf Medical's suppliers for immediate manufacture. Since all manufacturing is done on demand, it is possible to eliminate the need for inventory.



- 9 During the surgery, the guide instruments help the surgeon to find the correct orientation and placement of the implant. They provide support for simple and precise insertion of the implant at the correct angle and depth.

## Business idea, goals and strategy

Episurf Medical addresses significant medical needs not currently met by the orthopaedic industry, and the company's vision is to bring more people back to fully living life. The business implementation of this vision is to provide orthopaedic surgeons with clinically superior patient-specific treatments using Episurf Medical's proprietary image analysis, implant design and manufacture technologies. The Episealer® technology, now rapidly gaining traction in Europe on the strength of very promising study results, represents a unique treatment method for an orthopaedic treatment gap of significant size globally.



**VISION** Restore people to fully living life.



**BUSINESS IDEA** Provide orthopaedic surgeons with clinically superior patient-specific treatments.



**GOAL** The Board of Episurf Medical has resolved on financial and operational goals for the business, summarized below.

The long-term target is to achieve a 30% market share in the initially prioritized markets (US, Germany, UK, Nordics, Switzerland, Benelux and certain other EU markets). Within three years from market launch in the US market, Episurf look to reach a 15% market share in all prioritized markets. Episurf Medical estimates the total addressable market to be worth more than USD 1 billion<sup>1</sup> annually. There is a strong underlying growth in the market due to demographic factors and technological advancements. During the period up to FDA approval, the company targets substantial revenue growth on an annual basis. During this period, the company also expects to meet several important clinical and operational milestones, as Episurf expects to get more and more traction in the current markets, due to the presentation of clinical data, both long- and short-term, that continuously have been generated.

**For the purpose of achieving its goal and take steps towards fulfilling its vision, Episurf Medical has designed its strategy. The strategy rests on four key pillars:**



Clinical and health  
economical data supporting  
the Episealer® technology



Large user base of orthopaedic  
surgeons and KOL's



Secure reimbursement and  
production enabling attrac-  
tive margins



Technological and clinical  
relevance through a high  
degree of innovation

<sup>1</sup> The market potential for Episurf Medical's initial product portfolio Episealer® knee, in the initially prioritized regions in the US and in Europe, is estimated to be worth +USD 1bn, based on an estimated 350,000 potential patients p.a. and a price of USD 2.5k – 3.0k per implant.

## Strategy



### **Produce clinical and health economic data supporting the Episealer® technology**

Late 2017, the first peer-reviewed results from a multicenter study were published showing good-to-excellent results<sup>2</sup>. Additional case reports and patient follow-ups from patients who have exceeded three years since surgery strengthen our view that the Episealer® technology will deliver excellent long-term results. The Episealer® is evaluated in a number of clinical studies and the company is about to launch a large multicenter study in the US and in Europe. Episurf Medical is currently setting up an IDE (Investigational Device Exemption) clinical trial in US and European centers for the Episealer® knee implants. The study conducted under the IDE will form an important part of Episurf Medical's PMA (premarket approval) application to the FDA for US market approval.



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

The company is already present in selected European markets, and it has its plans for bringing the Episealer® technology to additional international markets, representing a mix of direct markets and distribution markets.

- » Episurf is considering additional global markets.
- » The company has engaged in distributor discussions in a number of Middle Eastern markets.
- » The company is in early distributor discussions for a number of Asian markets, following a regulatory review.
- » In the US market, the company has started a clinical study for the purpose of receiving FDA approval for marketing of the Episealer® technology. The study is conducted as a combined US and European multicenter study.



### **Secure production and reimbursement enabling high margins**

Securing reimbursement in relevant markets is a key success factor for the company and Episurf Medical will continue its work in selected markets. The company also continue its work towards improving gross margin. In the near term, investments are primarily directed towards software development and development of the company's IT platform. The company will invest in production capabilities when demand drives higher volumes.



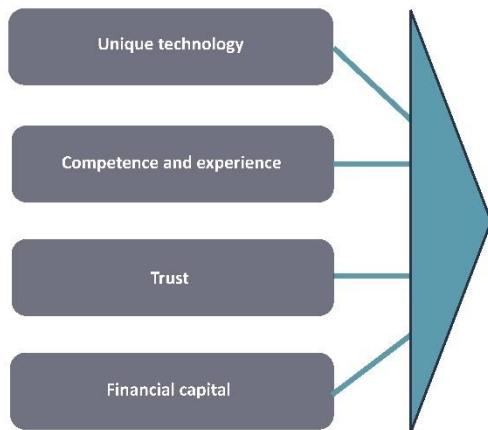
### **Ensure technological relevance and a high degree of innovation**

» Episurf Medical has decided to introduce a new joint implant to the market, and the company has developed a personalised implant for the ankle, which the company received the CE-mark for in January 2020. Episurf Medical is targeting a significant treatment gap for osteochondral ankle defects and the implant is based on the same technology platform as the company's knee implants.

<sup>2</sup> Stålmán, A., et al., No implant migration and good subjective outcome of a novel customized femoral resurfacing metal implant for focal chondral lesions. Knee Surgery, Sports Traumatology, Arthroscopy, 2017.

## Business model

### Inflow



**Episurf Medical**  
is analysing cartilage  
and bone lesions and  
manufactures  
patient-specific surgical  
tools and implants

### Outflow



## Our Clinical Advisory Board

Episurf Medical has appointed and works closely with an international Clinical Advisory Board as an important core group for the company's continuous efforts to pioneer the field of patient specific treatments. The advisory board consists of six key opinion leaders in the fields of cartilage repair and medical radiology.

### Episurf Medical's goals in working closely with the advisors are fourfold:

- » to gain a better understanding of the trends, drivers and priorities shaping clinical practice and the management of cartilage damage;
- » to validate Episurf Medical's value proposition and strategic direction thereby ensuring that the company's business is in sync with customer needs and expectations;
- » to review, assess and brainstorm product direction, improvement and development; and lastly,
- » to build robust and clinically evidenced patient outcome data.



**Ass. Prof. Tim Spalding**  
**United Kingdom**



Specialist Knee Surgeon, University Hospitals Coventry and Warwickshire NHS Trust and Honorary Associate Professor, Warwick Medical School, University of Warwick.



**Dr. Johannes Holz**  
**Germany**



Specialist in orthopaedics and trauma surgery, Ortho Centrum Hamburg, Parkklinik Manhagen.



**Professor Mats Brittberg**  
**Sweden**



Professor, Cartilage Research Unit, Gothenburg University, senior consultant orthopaedic surgeon, Department of orthopaedics, Kungsbäck Hospital, Kungsbäck.



**Professor Leif Ryd**  
**Sweden**



Orthopaedic surgeon with a long career in clinical research on osteoarthritis. Former Professor at Karolinska Institute.



**Dr. Adam Mitchell**  
**United Kingdom**



Radiologist at Forties Clinic, London who specialises in musculoskeletal imaging, with particular expertise in sports injuries.



**Ass. Prof. Karl Eriksson**  
**Sweden**



Senior consultant orthopaedic surgeon, Stockholm South Hospital, Associate Professor, Karolinska Institute, Stockholm, orthopaedic surgeon, Stockholm Knee Academy, Sophiahemmet Hospital, Stockholm.



**Professor Niek Van Dijk**  
**Spain / Netherlands**



Leading authority for arthroscopic surgery of the ankle. He is working in the FIFA Medical Centers of Excellence in Madrid, Clinic Ripol & DePrado & VanDijk and in Porto, Clinica De Dragão.

## Epioscopy®

Since the earliest conception of Episealer®, Episurf has understood the necessity of surgical pre-planning to ensure a perfect fit and function of the Episealer® implant. This pre-planning material has come to be known as our “Damage Marking Report”. Using the patient’s MR images, we create a virtual 3D model of the patient’s femoral knee or foot, visualising both cartilage lesions and bone damages underneath the cartilage. Throughout the years, we have continuously refined this report to the current digital platform we see today. The Damage Marking Report, or DMR as we call it, has always been a very appreciated tool by our customers as it enables them to clearly see the condition of the knee cartilage and the extent and exact position of lesions without having to resort to surgery. Some of our customers asked if we could refine it further to also include other structures in the knee or the foot which are otherwise generally surveyed during an arthroscopy.

### Driven by demand, engineered by science - our journey continues



Episurf took on the challenge and developed Epioscopy®. By combining the latest artificial intelligence (AI) technology with the experience we have of segmentation of MR images for device design and for visualisations in the Episealer® Damage Marking Reports, Epioscopy® can identify and visualise not only femoral knee joint cartilage and bone lesions but also such lesions in tibia well as defects on the cruciate ligaments and menisci. Epioscopy® is presented as an interactive online platform with a virtual 3D model of the knee or foot, correlating on-screen with the patient’s MR images.



*Epioscopy® introduces a new, modern way for healthcare professionals to look at the patient’s knee or foot and aims to aid them in their planning of optimal treatment options in a fast and easy way.*



*“Clever tuning of medical imaging sequences in combination with automation processes based on artificial intelligence has resulted in stunning anatomical and pathological visualisation. There are no limits within this field and Episurf is definitely a player here”, says Dr Adam Mitchell, Consultant Radiologist and member of Episurf Medical’s Clinical Advisory Board.*

## Market overview

*Episurf Medical's first patient-specific product portfolio, the knee portfolio, consists of the existing products Episealer® Condyle Solo and Episealer® Trochlea Solo, Episealer® Femoral Twin, and Epioscopy®. The first product portfolio is focused on treatment of cartilage damage in knee joints, and addresses a potential market worth many billions of US dollars. In January 2020, the company launched its second patient-specific product portfolio, the ankle portfolio. It consists of Episealer® Talus and Talus Osteotomy Guide.*

### About osteoarthritis

Osteoarthritis (OA) is the most common joint-related disorder and is characterised by the breakdown of cartilage in the joints. It is becoming increasingly widespread at the global level in pace with an aging population and a rising average body weight. Episurf Medical's existing products are primarily intended for patients in the age range of 30–65 years suffering from cartilage and underlying bone lesions in the knee joint (chondral and osteochondral lesions), who need to quickly return to an active life. There is a significant patient group with focal cartilage lesions of traumatic or degenerative origin (pre-OA) that today lacks adequate treatment alternatives and is in urgent need of effective new treatment methods. Left untreated, these lesions often develop into severe OA.

It has been reported that 12 percent of the population has osteoarthritis of the knee joint, while the corresponding figure for the ankle joint is 3.4 percent.<sup>3</sup>

### Market drivers

The market for treatment of cartilage and bone damages in joints is driven primarily by an aging population, a rising average body weight, technological advances in the design and manufacture of implant components that offer wider treatment options as well as technological advances in medical imaging leading to facilitated diagnosis. Since 1990 the human life expectancy on a global basis has risen by 6 years, from 62 to 68. Studies also show that the risk of developing osteoarthritis is doubled already at an excess weight of 7 kilos.<sup>4</sup> The World Health Organisation (WHO) estimates that 1.5 billion people over the age of 20 were overweight in 2008, of which more than 200 million men and 300 million women were obese.<sup>5</sup> The corresponding figure for 2015 is estimated at 2.3 billion overweight and more than 700 million obese.<sup>6</sup>

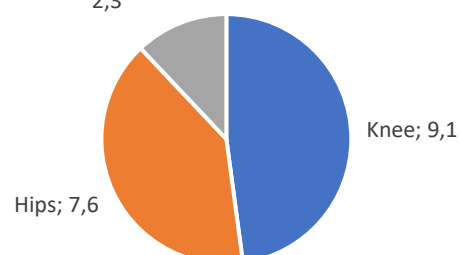
Customisation is a clear trend in the industry that is gaining an increasingly strong foothold in orthopaedics, just as in pharmaceuticals and healthcare. There are several explanations for this. New technology is opening whole new opportunities to combine industrial production with customised orthopaedic surgery. Many factors, such as patient demand, are driving changes among orthopaedic surgeons, in the healthcare sector as a whole and not least among insurance companies. The need for customisation is found throughout the chain from diagnostics to choice of treatment and design of implants. Improved preliminary diagnostics are needed to select the right type of treatment and more effective treatment solutions that are adapted to the patient. This offers potentially large savings for the healthcare sector and insurers.

### Existing treatment gap

The treatment of focal (isolated) chondral (cartilage) and osteochondral (comprising both cartilage and the underlying bone) defects of the knee joint can be challenging, especially in the middle-aged patient. There is a range of different treatments methods available, where factors such as the nature of the damage, severity of the symptoms, previous treatment history and patient age influence the decision of what is the proper treatment for the specific patient.

Biological treatments (such as microfracturing or autologous chondrocyte implantation, ACI) for chondral and osteochondral lesions of the articulating surfaces of the femoral knee joint typically give good results in younger patients but tend to perform less consistently and be less effective for osteochondral lesions and patients over 30–35 years of age. The most invasive procedure, used when no other treatment has succeeded, is partial or total knee joint replacement (unicompartmental knee arthroplasty, UKA/ total knee arthroplasty, TKA).

Figure 1. The global joint reconstruction market. Total 18.9bn US dollars  
Other joints; 2,3



Source: The Orthopaedic Industry Annual Report 2018

<sup>3</sup> Murray, C., et al., Population prevalence and distribution of ankle pain and symptomatic radiographic ankle osteoarthritis in community dwelling older adults: A systematic review and cross-sectional study. PloS one, 2018. 13(4): s. e0193662-e0193662.

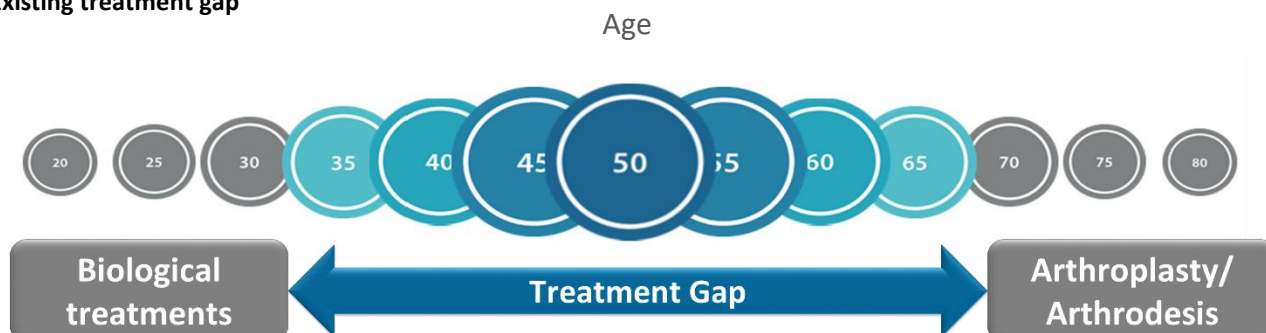
<sup>4</sup> <http://www.vetenskaphalsa.se/okad-risk-for-artros-aven-vid-latt-overvikt/>

<sup>5</sup> [http://www.who.int/gho/publications/world\\_health\\_statistics/2013/en/](http://www.who.int/gho/publications/world_health_statistics/2013/en/)

<sup>6</sup> [http://www.who.int/gho/publications/world\\_health\\_statistics/2013/en/](http://www.who.int/gho/publications/world_health_statistics/2013/en/)

Due to the high number of uncertain outcomes and high failure rates for knee cartilage pathologies for patients over 30-35 years of age, a treatment gap arises for a large group of patients; those who do not respond to biological interventions but who are still too young for partial or total knee arthroplasty (UKA/TKA).<sup>7</sup> Episurf Medical addresses this treatment gap with its unique damage marking report and patient-specific Episealer® product range.

#### Existing treatment gap



#### Knee joint

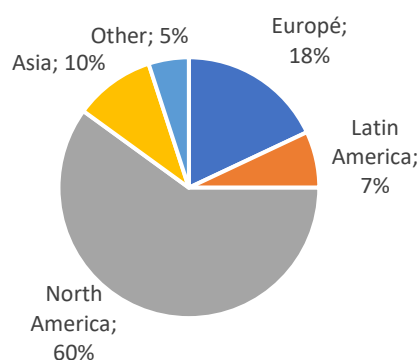
##### Global market for knee osteoarthritis

The global market for joint reconstruction, which includes revenue from several different joints such as the hips, knees, shoulders, elbows and ankles, amounted to around USD 18.1 billion in 2017. As a segment of this wider market, the market for knee products is the single largest and is worth approximately USD 8.8 billion per year. Within this market, knee implants (prostheses) is the largest product category in absolute terms. Episurf has established itself in this market with a primary focus on treatment of cartilage and joint damage of traumatic or degenerative origin from early cartilage lesions to initial OA, which in untreated condition often leads to full-scale OA. At present, the largest market for treatment of joint problems is that for late-stage OA. This is because the condition at that stage is so serious it must be treated, while the available treatment methods are relatively extensive and therefore costly. With modern MRI technologies diagnosis, and thus also treatment, can be made at an earlier stage.

Ten percent of the US population over the age of 25 has signs of OA in their joints, and half of that group is estimated to have knee OA.<sup>8</sup> According to studies reported, 5 percent of the US population over the age of 50 has a prosthetic knee joint.<sup>9</sup>

Over the past decade, the number of knee replacement procedures on patients under the age of 65 years has increased dramatically.<sup>10</sup> The ten largest markets for knee replacement surgery are the US, France, Germany, Italy, Spain, the UK, Japan, Brazil, China and India. About 1.5 million surgeries are performed

Figure 2. The global market for knee arthroscopies



Source: Transparency Market Research 2016

<sup>7</sup> Knutsen, G., et al., A Randomized Multicenter Trial Comparing Autologous Chondrocyte Implantation with Microfracture: Long-Term Follow-up at 14 to 15 Years. *Journal of Bone & Joint Surgery*, 2016. 98(16): p. 1332-1339. Weber, A.E., et al., Clinical Outcomes After Microfracture of the Knee: Midterm Follow-up. *Orthopaedic Journal of Sports Medicine*, 2018. 6(2): p. 2325967117753572. Kreuz, P.C., et al., Results after microfracture of full-thickness chondral defects in different compartments in the knee. *Osteoarthritis and Cartilage*, 2006. 14(11): p. 1119-1125

<sup>8</sup> Lawrence, R.C., et al., Estimates of the Prevalence of Arthritis and Other Rheumatic Conditions in the United States, Part II. *Arthritis and Rheumatism*, 2008. 58(1): p. 26-35

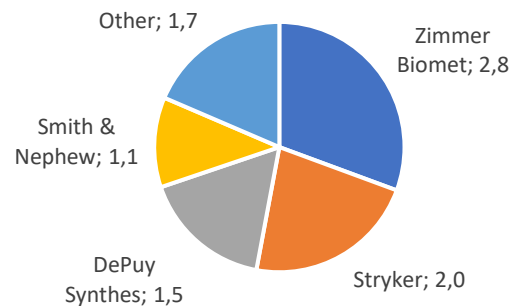
<sup>9</sup> <https://www.newswise.com/articles/knee-osteoarthritis-to-increase-in-younger-age-groups-in-next-ten-years>

<sup>10</sup> <https://www.newswise.com/articles/knee-osteoarthritis-to-increase-in-younger-age-groups-in-next-ten-years>

every year in these markets.<sup>11</sup> In 2016 some 1.2 million knee replacement surgeries were carried out in the US alone, which is more than a doubling in only 10 years.<sup>12</sup>

The prostheses used in knee replacement surgery today have an expected longevity of 15–20 years and in light of this, most orthopaedic surgeons recommend that patients wait until they have reached the age of 65 before undergoing this surgery. Furthermore, at present a small share is treated with partial knee replacement, in which half of the knee is replaced with a prosthetic joint. Partial knee replacement is not recommended for active patients at the ages of 40–60 years, since it wears out quickly. The number of partial knee replacements carried out per year in the US is around 115,000, which is around 10 percent of all knee replacements, and the number in Europe is around 80,000 per year.<sup>13</sup> There is an increasing trend of knee replacements on a global basis, with 2.6 million knee replacements performed in 2016, compared to 1.4 million in 2006.<sup>14</sup>

Figure 3. Market share in the global knee market. Total USD 9.0 bn



Source: Transparency Market Research 2018

### Episurf Medical's primary market potential – cartilage damage in the knee joint

Knee arthroscopy implies that an instrument is introduced through a small cut to investigate the inside of the joint and possibly correct any problems. Every year, around 6.5 million knee arthroscopies are performed worldwide and this number is expected to grow by an average of 7 percent annually over the next five years.<sup>15</sup> In the US alone, some 3.7 million knee arthroscopies are performed every year.<sup>16</sup> The corresponding figure for Europe is 1.1 million per year.<sup>17</sup> Research shows that of these knee arthroscopies, between 7–13 percent show traumatic or degenerative cartilage defects of ICRS grade III and IV<sup>18</sup>, implying that the cartilage defect extends down to >50 percent of the cartilage depth. Today it is assessed that around two-thirds of these are treatable with Episurf Medical's CE-approved knee implants Episealer® Condyle Solo, Episealer® Trochlea Solo and Episealer® Femoral Twin, depending on the location of the injury in the knee joint and the extent of the injury. Based on this, the company estimates the market potential for Episurf Medical's existing product portfolio to amount to approximately USD 3.5 billion over the coming years.

Episurf Medical's products are often used for treatment of patients in which arthroscopic treatment such as microfracturing or debridement has failed. This means, according to the company, further important market potential, based on the company's estimate that about 30 percent of the surgeries are regarded as failures within two years after surgery.

Episurf Medical's implants are designed to treat the patient's entire injury, both the cartilage and underlying bone defects, making it possible to address the underlying cause of the patient's pain more effectively than is currently possible using most of the alternative methods. It is the company's opinion that this indicates an increased probability that the company's implants will be increasingly accepted as the first line method for treatment of cartilage defects of ICRS grade III–IV, which in turn means that the market potential for Episurf Medical's products is growing.

<sup>11</sup> <http://newsroom.aaos.org/media-resources/Press-releases/knee-replacements-linked-to-obesity.htm>

<sup>12</sup> Global Data, Orthopedics Devices Market, Global

<sup>13</sup> Global Data, Orthopedics Devices Market, Global

<sup>14</sup> Global Data, Orthopedics Devices Market, Global

<sup>15</sup> Transparency Market Research 2016, Arthroscopy Procedures and Products Market – Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2015-2023

<sup>16</sup> Transparency Market Research 2016, Arthroscopy Procedures and Products Market – Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2015-2023

<sup>17</sup> Transparency Market Research 2016, Arthroscopy Procedures and Products Market – Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2015-2023

<sup>18</sup> Hjelle, K., et al., *Articular cartilage defects in 1,000 knee arthroscopies*. Arthroscopy: The Journal of Arthroscopic & Related Surgery, 2002. **18**(7): p. 730-734. Widuchowski, W., J. Widuchowski, and T. Trzaska, *Articular cartilage defects: Study of 25,124 knee arthroscopies*. The Knee, 2007. **14**(3): p. 177-182. Curl, W.W., et al., *Cartilage Injuries: A Review of 31, 516 Knee Arthroscopies*. Arthroscopy: The Journal of Arthroscopic & Related Surgery, 1997. **13**(4): p. 456-460. Årøen, A., et al., *Articular Cartilage Lesions in 993 Consecutive Knee Arthroscopies*. The American Journal of Sports Medicine, 2004. **32**(1): p. 211-215

## **The ankle**

### **The global market for ankle OA**

About 10 percent of the OA cases apply to the ankle and the trend for OA of the ankle is increasing<sup>19</sup>. OA of the ankle is often a secondary process that typically originates from an osteochondral injury to the articular surface of the talus bone in the ankle, as a result of severe trauma or repeated microtrauma. Patients are often slightly younger than those with knee joint OA, which implies that patients may have several decades ahead of them with ache and pain. Osteochondral ankle injuries occur most frequently at the age of 20-30 and are somewhat more common in men than in women<sup>20</sup>. Advances in medical imaging, an increase in the number of arthroscopies performed and increased participation in sports activities at higher ages entail that more and more of these injuries are being identified<sup>21</sup>.

### **Episurf Medical's market potential - osteochondral injuries in the ankle**

The company's ankle implant Episealer® Talus with its associated instrument set Episealer® Talus Toolkit and Talus Osteotomy Guide, which has been CE-marked separately as a product to facilitate osteotomy for access to and treatment of the medial talus, aim to treat osteochondral lesions in the talus bone in the ankle. These injuries often represent an early stage of OA. An American study shows an incidence of osteochondral lesions at the talus of 27 cases per 100,000 people<sup>22</sup>. This study has been conducted in the US military, so it can be assumed that the individuals in the study are highly active and the company therefore considers that the incidence in this study is greater than for the population in general.

### **Reimbursement**

The decision on which treatment or product to use for a patient is taken by the surgeon within the regulations that apply. These regulations vary from market to market but usually include both regulatory permissions to perform the treatment in the specific market as well as approval to receive financial reimbursement for the treatment.

Reimbursement is a word that is used generally in the healthcare industry to describe the payment systems that apply to healthcare costs in various countries. Most often, there are four parties involved; the patient, the responsible doctor, the hospital and the payer. The patient can also be the payer, although, it is quite rare for the patient to pay for the procedure out of pocket. Instead, there is normally a third party that reimburses the hospital and the doctor on behalf of the patient. This can be the government in the public healthcare system, or an insurance company if the patient has private health insurance.

### **When it comes to reimbursement, there are usually two different ways to introduce a new product in a market:**

- as a novel product; or
- as a product closely related to an existing product.

Which of these options that applies is generally decided by the responsible national authority with help from clinical and financial advisory groups. The decisions are based on the information and the clinical evidence of the product presented by the company.

The next step to get reimbursement for a product is that it is assigned a code. If it is concluded to be regarded as a novel product, a process that often takes 1-4 years is initiated, meanwhile temporary codes can be used with varying levels of compensation. If it is concluded to be closely related to an existing product, the same reimbursement level will apply as for the existing product.

Episurf Medical's knee implant, Episealer®, is based on existing and recognised treatment methods and materials, but is individualised and significantly more advanced than existing products. Therefore, it is not given how Episealer® is assessed in the different markets.

### **The current status of reimbursement for Episealer® Knee in Episurf Medical's main markets is as follows:**

- **Germany:** Existing codes for related products are used. The work is ongoing to reach a final decision on code and compensation level in the long term.

<sup>19</sup> <https://www.vetenskaphalsa.se/viktigt-att-valja-ratt-operation-vid-artros-i-fotleden/>.

<sup>20</sup> Tol, J.L., et al., Treatment Strategies in Osteochondral Defects of the Talar Dome: a Systematic Review. Foot & Ankle International, 2000. 21(2): s. 119-126.

<sup>21</sup> O'Loughlin, P.F., B.E. Heyworth, och J.G. Kennedy, Current Concepts in the Diagnosis and Treatment of Osteochondral Lesions of the Ankle. The American Journal of Sports Medicine, 2010. 38(2): s. 392-404.

<sup>22</sup> Orr J.D. et al. Incidence of osteochondral lesions of the talus in the United States military. Foot & ankle international 2011;32(10):948-54.

- **United Kingdom:** Since the start of the sale in the UK in 2015, existing codes for related products have been applied. Here, as well, work is ongoing to investigate the final code and level of reimbursement.
- **The Nordic countries:** The Nordic countries have reimbursement systems that are similar to each other, but differ from other European markets in that state hospitals often have a total annual budget, so decisions about treatment for the patient and which reimbursement code that should be applied is taken within the organisation. In Sweden and Denmark, a process is ongoing to ensure reimbursement for the Episealer®.
- **Belgium:** Episealer® has been approved by the national authority as closely related to an existing product and thereby a set reimbursement level is obtained.

Following the CE approval for Episealer® Talus, work has now been initiated (according to the processes for Episealer® knee described above), to identify suitable reimbursement codes in each market. The company's initial assessment is that there are existing codes, in all major markets, where the reimbursement is high enough to justify a product launch.

## Episurf Medical's product portfolio

*As a pioneer in patient-specific technology for the treatment of painful joint injuries, Episurf Medical does something that no other resurfacing implant manufacturer has done. We put the patient in the centre of the design of implants and surgical instruments.*

Episurf Medical's implant portfolio includes products that can be used to treat patients in the age group 30–65 years with knee joint, ankle cartilage injuries of most types and sizes, from initial cartilage damage to early OA.

By combining advanced 3D imaging technology with the latest manufacturing technologies, not only each implant is adapted to the patient's unique injury and anatomy, but also the surgical instruments used. In this way, it can be ensured that every patient receives treatment that is perfectly suited to his or her anatomy and thus ensuring a faster, more secure and better patient-specific treatment for a more active and healthy life.



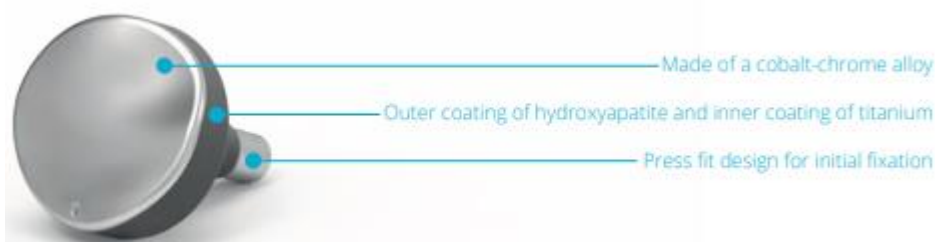
### The Episealer® implant system consists of the following:

- Episealer® implant
- Episealer® toolkit
- Damage marking report

### Episealer® implant

Episealer® implants are adapted to each individual's unique anatomy and injury. They are made of a cobalt-chrome alloy with a central peg for initial fixation (two pegs for Episealer® Femoral Twin). Cobalt-chrome is a material that has been used in knee prostheses for more than two decades and has been proven to provide a safe, effective and weight-bearing joint surface. The design of the Episealer® implants has been selected for firm short-term and long-term fixation, to minimise the risks of revision due to implant loosening. The Episealer® implants are inserted press-fit for immediate fixation and the implants achieve early post-operative fixation thanks to the hydroxyapatite (HA) layer, and additionally further long-term fixation due to the titanium (Ti) layer beneath.

The use of HA coatings has advantages compared to the use of acrylic bone cement, such as a simpler surgical procedure, avoidance related to risks of mechanical degradation of the acrylic cement and adverse tissue response initiated by thermochemical side effects of the acrylic cement. The Episealer® implants with the double coating (Ti + HA) have been evaluated in sheep studies.<sup>23</sup> In one of these publications adherence between cartilage and the HA-coated implant was reported, and a concept of sealing of the interface between cartilage-bone and implant is discussed. This effect can prevent joint fluid from penetrating the metal-bone interface and thus minimise risks of osteolysis and cyst formation. The sealing effect with bonding between the HA-coated implant edge and cartilage has been confirmed in a subsequent sheep study.



As far as the company is aware, the competitive resurfacing devices primarily address cartilage lesions, whereas Episealer® addresses both the cartilage lesion and the underlying bone defect. Since cartilage does not have any nerve fibres, pain signals do not originate from the cartilage but in most cases from a lesion in the bone underneath. If one fails to treat the underlying bone defect adequately, the pain may persist. Conversely, treating patients without a bone lesion may not result in relief of pain, which, in those cases, originates from somewhere else in the joint.

One of the most important risk mitigations for Episealer® compared to all other resurfacing implants, is that the clinical situation in the knee is reviewed in advance by an Episurf Medical radiologist and compiled into a damage marking report, which is communicated directly with the surgeon. The probability for inappropriate cases (i.e., usage outside the intended use), is thus improbable.

Using a patient-specific damage marking report and CAD-CAM technology, the Episealer® is designed based on the patient's specific anatomy and lesion, ensuring a perfect fit to avoid damaging of the opposing cartilage.

<sup>23</sup> Martinez-Carranza N, Berg HE, Lagerstedt AS, Nurmi-Sandh H, Schupbach P, Ryd L. Fixation of a double-coated titanium-hydroxyapatite focal knee resurfacing implant: A 12-month study in sheep. *Osteoarthritis and Cartilage*. 2014;22(6):836-44 och Schell H, Jung TM, Ryd L, Duda G. On the attachment of cartilage to HA: signs of "chondrointegration" studies on a novel mini-prosthesis in the sheep knee. *Knee Surg Sports Traumatol Arthrosc*. 2016;24(Suppl 1):S387-S8.

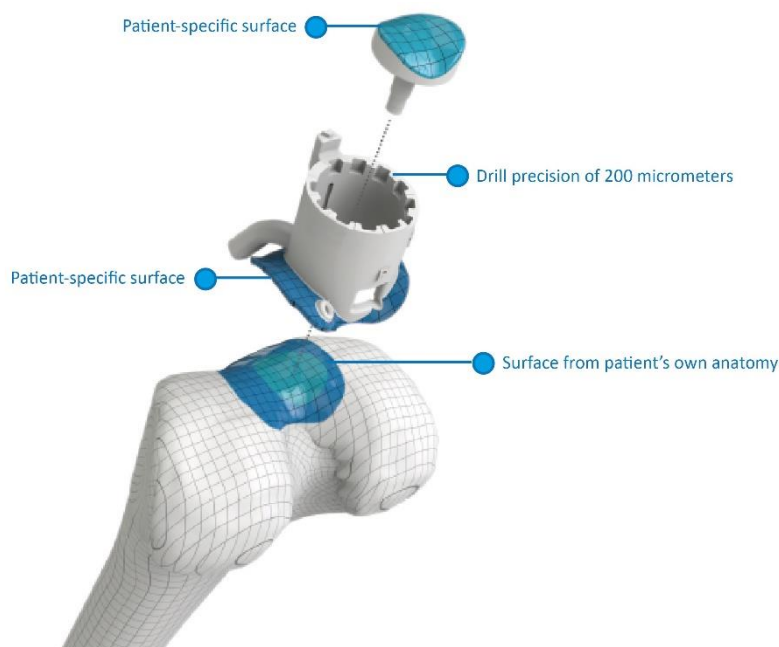
Competitive, off-the-shelf products might not, according to the company, fit precisely as the surgeon selects the shape/size that fits best based on intra-operative measurements of the lesion size and joint anatomy. This will not ensure a perfect fit which may compromise the clinical outcome of the surgery. Further, more lesions/implant positions in the joint can be addressed with the truly patient-specific Episealer®, providing unlimited choices of implant surface curvature.

### Episealer® Toolkit

*Customised surgical tools for high precision*

**CORRECT POSITIONING OF THE IMPLANT** is obtained by means of a corresponding, patient-specific toolkit, to assist the surgeon during surgery. The proprietary Episealer® toolkit is an inherent part of the Episealer® procedure. The toolkit supports the precise implantation of the Episealer®, and each Episealer® implant has a toolkit CE-marked along with the Episealer® implant.

To ensure simple and fast surgery and optimal positioning of the implant, Episurf Medical delivers a customised drill guide for each procedure, the Epiguide®. It is designed according to patient-specific data in the same way as the Episealer® and delivered to the clinic together with the implant. The guides are designed to deliver a custom fit and can thus be easily placed in the joint over the damaged area. They are essentially a mirror image of the patient's joint surface around the damaged site. The guide is designed so that the drilling angle and depth are predetermined, these are thus not a matter of judgement for the surgeon. Epiguide® guides the surgeon through the entire procedure, simplifies execution and increases precision.



### Damage marking report

Customisation of the Episealer® with respect to implant size (diameter and thickness) and articular surface curvature is supported by the creation of a damage marking report. This report is generated using medical images and a virtual 3D model of the patient's knee or ankle which enables pre-operative planning and individual customisation of implant and surgical tools. The report allows for a distinct establishment of indications and contraindications, to ensure that only patients suited for the procedure are operated.

To make this possible, an MRI (for knee/ankle) or CT (for ankle) scan of the patient's knee or ankle is performed, anonymised and sent digitally to Episurf Medical through the order management system µiFidelity®. The quality of the MR/CT images is checked. Based on the MRI/CT data, the geometry of the joint as well as the extent of the damage are assessed and visualised together with an Episurf Medical radiologist.

A virtual 3D model of the affected joint, including possible lesions, is created. The report is subsequently compiled and delivered to the treating surgeon through µiFidelity®. The report is used by the treating surgeon as an assessment support tool and for planning of the appropriate surgery.

Upon confirmation from the treating surgeon and approval of the case, the patient-specific implant and corresponding tools are designed and manufactured. In case the report concludes that the patient is regarded not suitable to receive an Episealer®, the surgeon will be notified and given an explanation.



### Possible future areas of use

Episurf Medical is working actively to develop and widen the product portfolio into new application areas where there may be opportunities to apply the company's technology and expertise within individualised treatment. The company's technology can be applied to joints other than the knees and ankles such as shoulders, toes and even hips, and can thus give rise to additional product portfolios for specific areas of use.

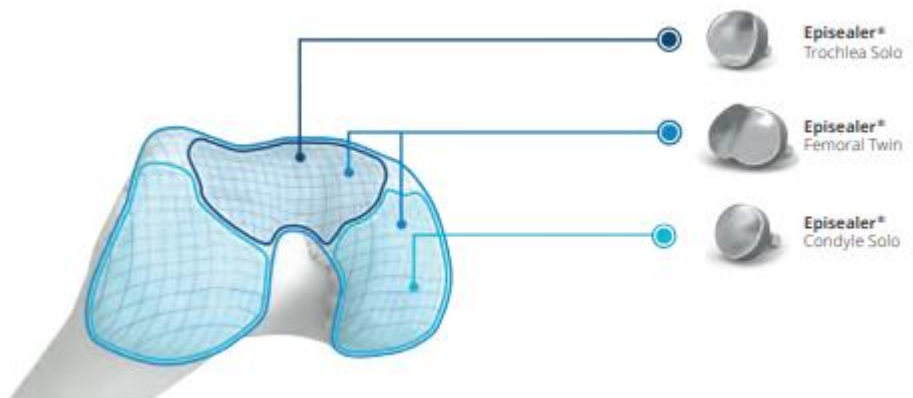
### Product for the knee

#### Episealer® individualised implants

##### Episealer® knee implants

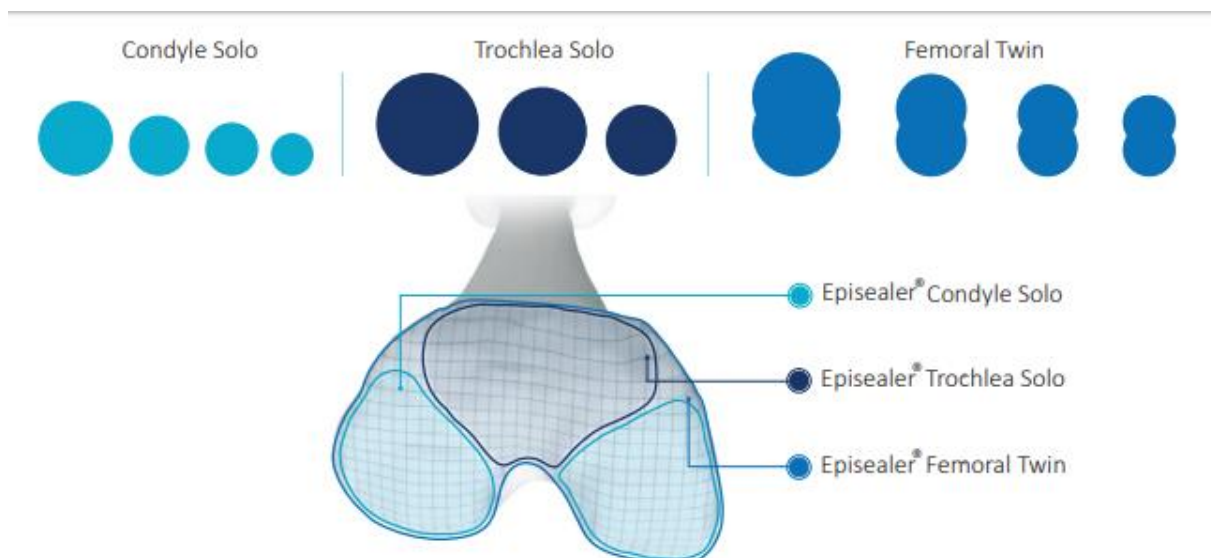
Episurf Medical's Episealer® knee implants make it possible to repair focal cartilage and bone defects to reduce pain and increase mobility in the patient's knee joint. Episealer® implants can be easily inserted, cause minimal trauma to the surrounding tissue and require less complicated rehabilitation than the other treatment alternatives. Furthermore, since healthy cartilage and bone are preserved and the implant has a neat design, the patient's options for future interventions, such as for example knee replacement surgery, are not limited.

Episurf Medical's technique tailors the implant to each individual patient instead of forcing the patient to fit the implant, as is traditionally done in joint resurfacing surgery. The implant is built on the idea that all patients have unique anatomies. Small variations in the size and placement of an implant can have a significant impact on the short- and long-term outcomes of a procedure.



#### The Episealer® knee implants constitute a family of individually customised, patient-specific, metallic resurfacing implants including the following:

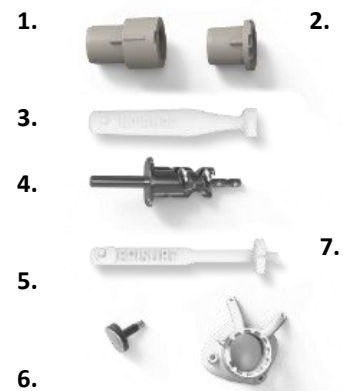
- » Episealer® Condyle Solo (CE-marked, Class IIb, year 2013)
- » Episealer® Trochlea Solo (CE-marked, Class IIb, year 2014)
- » Episealer® Femoral Twin (CE-marked, Class IIb, year 2015).



## Episealer® toolkit for the knee

The single use toolkits for the implants consist of the following parts:

- 1) Drilling socket – insert to be used with the Epiguide® to guide the Epidrill for initial drill depth
- 2) Adjustment socket – insert to be used with the Epiguide® to guide the Epidrill for exact depth adjustment
- 3) Epimandrel – tool to assist insertion of the implant
- 4) Epidrill – drill
- 5) Epidummy – replica of the Episealer® for depth control
- 6) Episealer®
- 7) Epiguide® – drill guide, aids the surgeon to obtain the exact drilling access and depth, to ensure the correct placement of the implant. For Episealer® Femoral Twin there is one additional part included, the Epiguide® insert.



## Product for the ankle

### Episealer® Talus

*Driven by demand, engineered by science*

Based on the technical, pre-clinical and clinical experiences from the Episealer® knee implants, Episurf Medical has evolved the technology further and has launched a solution for treatment of bone and cartilage defects in the talus bone of the ankle joint.

### The ankle joint

The ankle joint is a place where three bones meet; tibia (shin bone), fibula (calf bone) and talus (ankle bone). Like in the knee, the cartilage in the ankle joint is susceptible to wear and tear. Cartilage and bone defects on talus have been a challenge to orthopaedic surgeons due to lack of reliable treatment alternatives. Total joint replacement with an ankle prosthesis does not provide the same range of motion as the original joint and this is followed by an increased risk of arthrosis in the forefoot. And as for the knee, the ankle joint prostheses have a limited lifetime. Ankle arthrodesis (ankle fusion) is an alternative treatment, but implies risks of adverse effects such as non-union and arthrosis in other joints. These factors indicate that it is highly motivated to restore the original joint.

### Episurf Medical's solution

Episurf Medical's engineers have, together with some of the most experienced foot and ankle specialists in Europe, developed an Episealer® system for the ankle joint. The Episealer® implant is the same as for the knee joint, only adapted for the curvature of the talar dome. Episealer® Talus received its CE approval Class IIB, in 2020.

One of the challenges with talar lesions has previously been to get access to the difficult-to-reach medial side of talus due to its position under the shin bone. Thanks to a novel individualised osteotomy guide (saw guide), developed by Episurf Medical and designed and manufactured with the same imaging and 3D technology as the Episealer® drill guide, Epiguide®; it is now easier for the surgeon to temporarily remove the medial malleolus (a part of tibia) and get access to talus. The design of the unique osteotomy guide further prepares for easy re-fixation of the malleolus after performed Episealer® implantation.

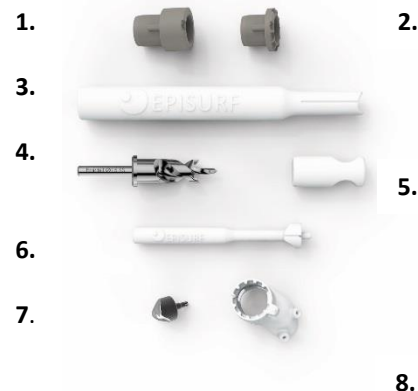
As with the Episealer® knee family, Episurf Medical's proprietary set of surgical instruments is provided together with the implant to give the surgeon support with the critical moments, to ensure a desired implant placement and restoration of the anatomy.



### Episealer® toolkit for the ankle

The single use toolkits for the Episealer® Talus implants consist of the following parts:

- 1) Drilling socket – insert to be used with the Epiguide® to guide the Epidrill for initial drill depth
- 2) Adjustment socket – insert to be used with the Epiguide® to guide the Epidrill for exact depth adjustment
- 3) Epimandrel – tool to assist insertion of the implant
- 4) Epidrill – drill
- 5) Pin socket – Insert used with Epiguide® to control drilling of a guide hole for Epidrill
- 6) Epidummy – replica of the Episealer® for depth control
- 7) Episealer®
- 8) Epiguide® – drill guide, aids the surgeon to obtain the exact drilling access and depth, to ensure the correct placement of the implant

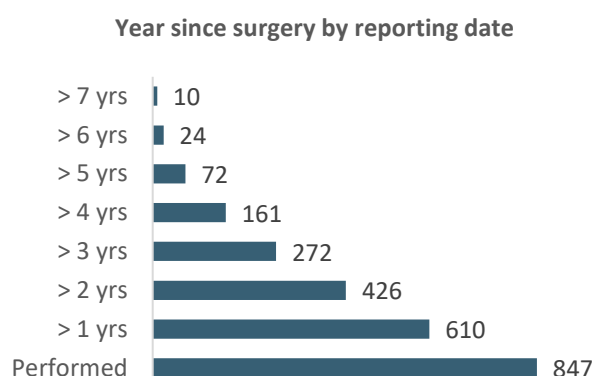


#### Statement by Professor Leif Ryd

*"There is a great demand for this implant, as there are few alternatives for lesions in the ankle. In many cases, patients with these injuries are forced to undergo joint fusion. It feels fantastic to finally be able to offer our solution. This is an example that Episurf's technology in principle can be applied to all joints".*

## Clinical evidence

### Number of surgeries and years since surgery by reporting date



Since the first day of development of the Episealer®, research has held the highest priority. As part of that development, four preclinical studies<sup>24</sup> have been conducted to ensure that Episurf's concept is viable and to make certain that Episealer® was ready for clinical use. Subsequently, another preclinical study, three clinical studies and a survival analysis based on the results of over 600 implants, were performed. These results have now been published in scientific journals.

The first four preclinical studies were performed by MD PhD N. Carranza at Karolinska University Hospital. The studies<sup>25</sup> highlight the importance of exact placement of the implant, the value of the implant being adapted to the patient's unique anatomy and how the bone grows firmly into the implant thanks to the surface treatment of titanium and hydroxyapatite. One of the studies also indicated that the hydroxyapatite could stimulate the cartilage to grow firmly into the implant and create a sealing effect that prevents the synovial fluid from being pressed under the implant and creating loosening. The ability of hydroxyapatite to contribute to the integration between the implant and the cartilage in the patient's knee was also later proven in a publication by H. Shell et al. at the Julius Wolff Institute, Charité University Hospital, Berlin, Germany<sup>26</sup>.

The very first patient to receive the Episealer® knee implant underwent surgery in December 2012. He was one of 10 patients included in Episurf's first clinical study<sup>27</sup>, which resulted in the publication "No implant migration and good subjective outcome of a novel customized femoral resurfacing metal implant for focal chondral lesions" by A. Stålmán et al. published in *Knee Surgery, Sports Traumatology, Arthroscopy (KSSTA)* in November 2017. The study is summarised with "Good implant safety and satisfied patients, significantly improved knee function and reduced pain".

It takes time to obtain clinical results, therefore the Company is today grateful for the cooperation with the early users who followed up their patients and compiled their results for publication. This has resulted in the publication in the past year of two independent clinical studies with a follow-up of over 100 patients.

In October 2020, the manuscript entitled "Patient specific metal implants for focal chondral and osteochondral lesions in the knee - Excellent clinical results at 2 years" was published in the prestigious scientific journal *Knee Surgery, Sports Traumatology, Arthroscopy (KSSTA)*. The study reports on the clinical results for 80 patients from 9 clinics in 6 European countries, who have undergone treatment with the individualised knee implant Episealer® for limited

<sup>24</sup> Martinez-Carranza, N., et al., Focal knee resurfacing and effects of surgical precision on opposing cartilage. A pilot study on 12 sheep. *Osteoarthritis and Cartilage*, 2013. 21(5): s. 739-745. Martinez-Carranza, N., et al., Fixation of a double-coated titanium-hydroxyapatite focal knee resurfacing implant: A 12-month study in sheep. *Osteoarthritis and Cartilage*, 2014. 22(6): s. 836-844. Martinez-Carranza, N., et al., Treatment of full thickness focal cartilage lesions with a metallic resurfacing implant in a sheep animal model, 1 year evaluation. *Osteoarthritis and Cartilage*, 2016. 24: s. 484-493. Martinez-Carranza, N., et al., Cartilage Health in Knees Treated with Metal Resurfacing Implants or Untreated Focal Cartilage Lesions: A Preclinical Study in Sheep. *CARTILAGE*, 2019. 10(1): P. 120-128.

<sup>25</sup> Martinez-Carranza, N., et al., Focal knee resurfacing and effects of surgical precision on opposing cartilage. A pilot study on 12 sheep. *Osteoarthritis and Cartilage*, 2013. 21(5): s. 739-745. Martinez-Carranza, N., et al., Fixation of a double-coated titanium-hydroxyapatite focal knee resurfacing implant: A 12-month study in sheep. *Osteoarthritis and Cartilage*, 2014. 22(6): s. 836-844. Martinez-Carranza, N., et al., Treatment of full thickness focal cartilage lesions with a metallic resurfacing implant in a sheep animal model, 1 year evaluation. *Osteoarthritis and Cartilage*, 2016. 24: s. 484-493. Martinez-Carranza, N., et al., Cartilage Health in Knees Treated with Metal Resurfacing Implants or Untreated Focal Cartilage Lesions: A Preclinical Study in Sheep. *CARTILAGE*, 2019. 10(1): P. 120-128.

<sup>26</sup> Schell, H., et al., Treatment of osteochondral defects: chondrointegration of metal implants improves after hydroxyapatite coating. *Knee Surgery, Sports Traumatology, Arthroscopy*, 2019. 27(11): s. 3575-3582.

<sup>27</sup> Stålmán, A., et al., No implant migration and good subjective outcome of a novel customized femoral resurfacing metal implant for focal chondral lesions. *Knee Surgery, Sports Traumatology, Arthroscopy*, 2018. 26(7): s. 2196-2204.

cartilage and bone injuries in the knee joint. The authors, led by Dr. Med. Johannes Holz, Park-Klinik Manhagen, OrthoCentrum, Hamburg, Germany, consists of some of the most experienced Episealer® users and the most knowledgeable European knee specialists. The authors of the publication have evaluated the clinical outcomes for the patient group using the patient-reported outcome measures KOOS (Knee Injury and Osteoarthritis Outcome Score) and VAS (Visual Analogue Scale). In KOOS, all measured subdomains, including pain, symptoms, function in daily life, function in sports and recreation, and quality of life, showed significant improvement. The authors of the publication concluded that the Episealer® implants provide significant clinical and functional improvement. They also find that the study indicates that there is a definite place for Episealer® in the treatment algorithm of cartilage defects in the knee joint.

The above publication was later that month followed by the publication "Successful Treatment of Femoral Chondral Lesions with a Novel Customized Metal Implant at Midterm Follow-Up" which was published in the focused scientific journal Cartilage. The study was led by chief investigator MD PhD A. Ståhlman at Capio Artro Clinic, Stockholm, with MD PhD N. Carranza as first author, and reports on the results from a follow-up of 30 of the first Episealer® patients from nine Swedish clinics. The patient-reported follow-up results EQ5D VAS (EuroQoL Visual Analogue Scale), VAS-pain (Visual Analogue Scale) and KOOS (Knee Injury Osteoarthritis Outcome Score) all show significant improvements. The study also showed promising survival rate results with only 3% revised at an average follow-up of 55 months.

In December 2020, a manuscript based on a post-market surveillance of the knee implant Episealer was approved for publication in the scientific journal Surgical Technology International. The publication with the title "Patient-specific implants for focal cartilage lesions in the knee: implant survivorship analysis up to seven years post-implantation" by L. Ryd, K. Flodström and MT Manley, is based on the result from more than 650 Episealer procedures and shows a cumulative survival rate of > 96% over seven years.

In summary, the above publications demonstrate that the company now can present unique results in terms of the combination of clinical / functional improvement and low revision frequency. There are a number of study initiatives in pipeline and one of the most prioritised initiative is our IDE study, a study initiated to support Episurf Medical's strategic goal to receive FDA (Food and Drug Administration) approval and launch the Company's products in the US market, which is the world's largest orthopaedic market. Please find more information in the specific chapter dedicated to our preparations for entrance into the US market on page 26.

Further on, Ass. Prof. Tim Spalding, at University Hospitals Coventry and Warwickshire NHS Trust, has initiated a five-year follow up of the 50 first patients in the above mentioned study, "*Patient specific metal implants for focal chondral and osteochondral lesions in the knee - Excellent clinical results at 2 years*" by Holz et al. The aim is to complete this study and submit a manuscript for publication in 2022.

In 2020, our most recent product Episealer Talus was launched. Prof. Niek van Dijk, active at FIFA Medical Centers of Excellence in Madrid, has initiated a prospective multicentre study with five-year follow up of 25 Episealer Talus patients. This study is highly important for us and we feel honoured that Prof. van Dijk has taken this initiative.

Together with the recently published evidence and the comprehensive research performed in the development phase of the Episealer technology, we are confident that our clinical pipeline will provide the evidence required in order continue the market expansion and continue to show the unique performance of our implant portfolio.

### Preparations for entrance into the US market

Episurf Medical has a strategic goal to receive FDA (Food and Drug Administration) approval and launch the company's products in the US market, which is the world's largest orthopaedic market. In order to receive FDA approval Episurf Medical needs to provide adequate clinical evidence that demonstrates that Episealer® constitutes a safe and effective treatment alternative for its intended use.

In July 2016 Episurf Medical participated in a so-called pre-submission meeting with the FDA in Washington D.C. After the meeting Episurf Medical submitted a 513(g) request for information in order to get an assessment from the FDA regarding classification and regulatory requirements that are applicable for the knee implant Episealer®. In 2017 the company received the FDA's response to the 513(g) request and the company decided to work towards FDA approval through a process known as PMA (Premarket Approval). A PMA-process is based on the product demonstrating its safety and effectiveness through an adequate and closely monitored clinical trial. The PMA process is the most stringent regulatory route and is required for products classified as Class III.

The first step in a PMA process is to seek IDE (Investigational Device Exemption) approval in order to receive permission to start a clinical trial. An IDE submission undergoes a regulatory review process where the clinical protocol along with the proposed study design constitutes a part of a larger material sent to the FDA for examination. In 2018 the company submitted an IDE request for the knee implant Episealer® and thereafter received feedback from the FDA. The company continued to work on responses to FDA's questions and in 2018 received approval to initiate the clinical trial. The letter from the FDA granted conditional approval which implies that Episurf Medical's IDE study can commence, and enrolment of patients can begin as soon as all preparations are in place including ethics approvals. Additional minor questions still need to be resolved before full approval is received, however there are no concerns that prevented the FDA from granting approval of study design and initiated patient recruitment for the clinical trial. In 2019 the company dealt with most of these issues and in 2020 the full approval from the FDA was received.

The clinical trial that has now been initiated is conducted both in the US and Europe. The study is a randomised, controlled study with the biological treatment method microfracturing as the control group. Patients will be followed over two years and the study will involve 180 patients. A clinical study conducted in the United States is of utmost importance for the company, both as part of the FDA approval process, but also to prepare for future reimbursement in the United States and to strengthen the clinical evidence for sales purposes and reimbursement in other markets.

This clinical trial is referred to as the "EPIC-Knee study" and the first surgery was performed in September 2020. Extensive preparations were performed during 2019 and 2020 including study documentation preparations, contract negotiations, ethical approvals, surgical training etc. The company has appointed a lead investigator for the entire IDE study in Dr Kevin Plancher in New York. The patient recruitment was during 2020 heavily influenced by the COVID-19 pandemic but the company is hoping to have great progress in patient recruitment during 2021.



## Strategic advisors



### **DR MICHAEL MANLEY**

Dr Manley has been with Stryker Orthopaedics since 1987, was Chief Scientific Adviser until December 2016 and remained a consultant to the company in certain areas. After three decades, Dr Manley has extensive experience in the fields of clinical studies, regulatory processes, and procedures along with research and developmental science.

Dr Manley advises the company on a broad range of topics related to its US strategy.



### **DR MICHAEL A KELLY**

Dr Kelly is the Chairman of the Department of Orthopaedic Surgery at The Hackensack University Medical Center in New Jersey and was previously President of the prestigious American Knee Society. He is the founding Professor and Chairman for Orthopedic Surgery at Hackensack Meridian School of Medicine at Seton Hall University.

Dr Kelly's practice is focused on all aspects of knee surgery and, he is the author of numerous scientific articles within the field. He co-edited the textbook Surgery of the Knee 2nd Edition. Dr Kelly has lectured throughout the US and internationally on topics related to sports medicine and knee reconstruction and, he is a member of many professional organizations, including the American

Orthopaedic Society of Sports Medicine and the American Orthopaedic Association. Previously, Dr Kelly served as the head team physician of the New Jersey Nets in the NBA (National Basketball Association). Dr Kelly is a graduate from Georgetown University School of Medicine.

Dr Kelly advises the company on a broad range of topics related to its IDE study and US launch.



### **NILES NOBLITT**

Niles Noblitt is a Senior Advisor to the company and one of the founders of Biomet, a part of the global orthopaedic market leader Zimmer Biomet. For about 30 years, Niles Noblitt was also the Chairman of Biomet.

As a Senior Advisor to Episurf Medical, Niles Noblitt assists the company on matters relating to the global strategy, partnerships, and operational development.



### **PROF. DOCTOR JOÃO ESPREGUEIRA-MENDES**

Prof. Doctor João Espregueira-Mendes has extensive experience from the global orthopaedic markets and is currently the Clinical Director of Clínica do Dragão - Espregueira-Mendes Sports Center, FIFA Medical Center of Excellence. He is also the Coordinator and Professor of Orthopedics at the University of Minho as well as treasurer of the International Society of Arthroscopy, Knee Surgery and Orthopedic Sports Medicine (ISAKOS). Prof. Doctor João Espregueira-Mendes currently serves as a member of the board of the Patellofemoral Foundation and FIFA Medical Centers of Excellence.

Prof. Doctor João Espregueira-Mendes advises Episurf regarding the establishment of the Episealer® knee technology in India and Portugal.

## Organisation and employees

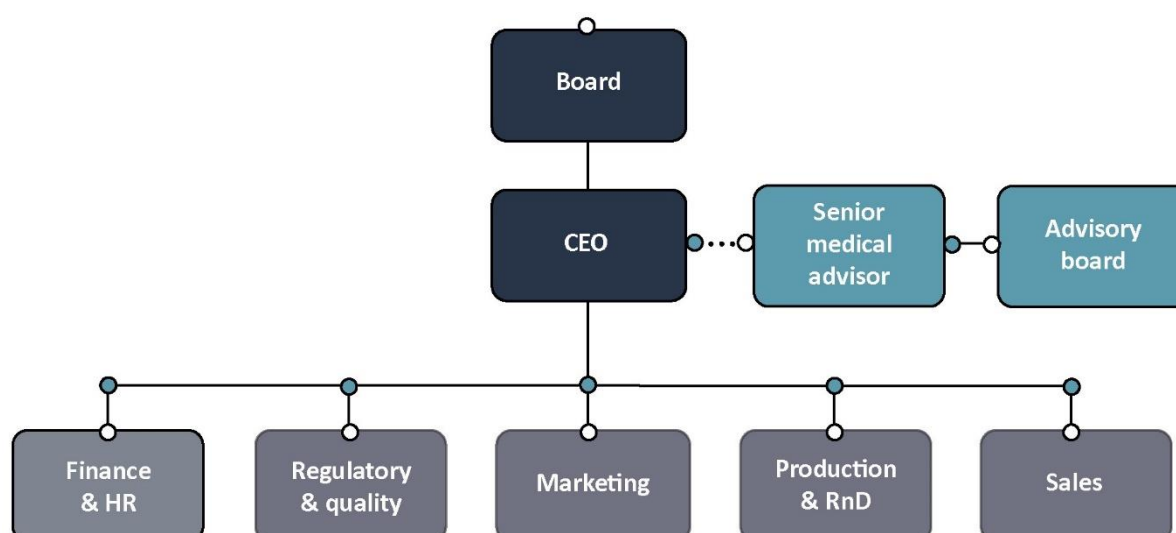
The Group consists of Episurf Medical AB (publ), which is the parent company of the Group, and the wholly owned subsidiaries Episurf IP-Management AB, Episurf Operations AB, Episurf Europe AB, Episurf DE GmbH, Episurf Medical Inc, Episurf India Limited and Episurf Europe AB's wholly-owned subsidiary Episurf UK Ltd.

**THE AVERAGE NUMBER OF EMPLOYEES** in the Group during 2020 was 25, of whom 10 women and 15 men. The number of employees in the Group at the end of 2020 was 25, which is the same compared to year end 2019.

Despite its limited size in terms of the number of employees, Episurf Medical's organisation possesses considerable expertise in most areas of relevance to the company. Long experience is found in areas like clinical research, international sales of orthopaedic implants and design and development of customised implants. As a means for gaining access to additional expert know-how and to minimise costs and maintain the desired flexibility, Episurf Medical uses external consultants to a certain extent. Furthermore, the company collaborates with a number of experts in different fields.

This structure enables the company to allocate resources according to need and to bring in the right expertise at the right time. As more products enter the launch phase, the company adds more functions to the in-house organisation.

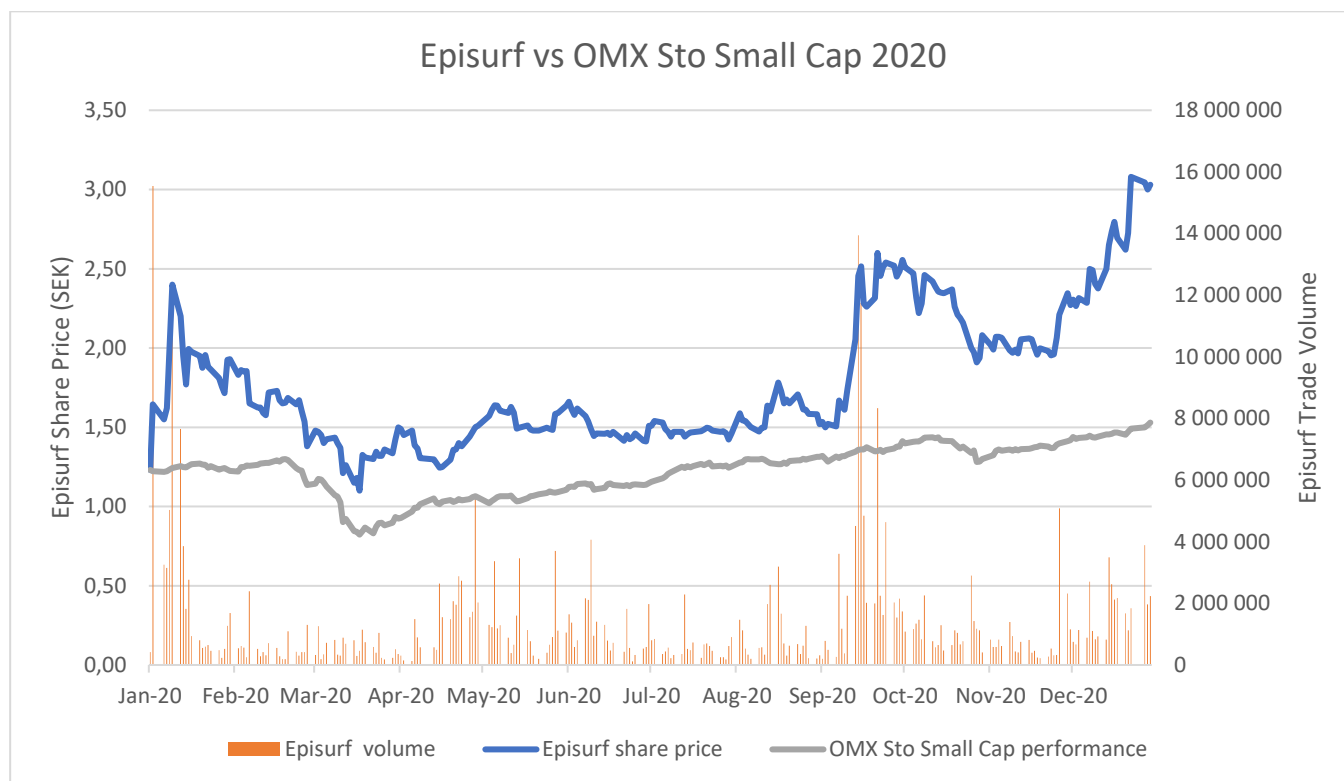
On May 1, 2020, the company's sales director Göran Martinsson assumed a new role as head of distribution markets, and the company's CEO was also appointed acting sales director. In connection with the role changing, Göran Martinsson left the management team.



## Share capital and ownership structure

Episurf Medical's share is listed on Nasdaq Stockholm, Small Cap, since 2014.

### Share price performance during 2020



### General information

The company's shares are issued in two classes. As of December 31, 2020, the company's registered share capital amounts to SEK 66,668,546.29 distributed among 917,024 A-shares (ISIN: SE0003523869) and 221,069,519 B-shares (ISIN: SE0003491562), corresponding to a total of 222,040,543 shares. The quota value of each share is SEK 0.3. According to Episurf Medical's current articles of association 31 December 2020, the share capital may not be less than SEK 27,302,316.80 and not more than SEK 109,209,267.20 represented by no less than 90,930,755 shares and no more than 363,723,020 shares.

During the year, the company carried out one rights issue, two directed issues and conversions of warrants. See more information under "Share issues and share conversions" below.

The company's B share is traded on Nasdaq Stockholm since 11 June 2014 under the ticker symbol "EPIS B". The shares in the company have been issued according to Swedish law and are denominated in SEK. The company's shares are registered in a CSD register in accordance with the Swedish Act on Central Securities Depositories and the Accounting of Financial Instruments (Sw. lagen (1998:1479) om värdepapperscentraler och kontoföring av finansiella instrument). This register is managed by Euroclear Sweden AB. No share certificates have been issued for the company's shares.

## The ten largest shareholders by voting rights in Episurf Medical at December 31, 2020

| Name                                   | No. Of A-shares | No. Of B-shares    | Share capital in % | Voting rights, % |
|----------------------------------------|-----------------|--------------------|--------------------|------------------|
| Skandinaviska Enskilda Banken, W8IMY   | -               | 10,563,208         | 4.8                | 4.7              |
| Försäkringsbolaget, Avanza Pension     | -               | 10,474,756         | 4.7                | 4.7              |
| Fjärde AP-Fonden                       | -               | 10,450,000         | 4.7                | 4.7              |
| Nordnet Pensionsförsäkring AB          | -               | 8,090,452          | 3.6                | 3.6              |
| Banque Pictet & Cie (Europe) SA, W8IMY | -               | 7,980,002          | 3.6                | 3.6              |
| Tredje AP-Fonden                       | -               | 7,900,000          | 3.6                | 3.5              |
| SEB Life International                 | -               | 6,000,000          | 2.7                | 2.7              |
| Andra AP-Fonden                        | -               | 5,400,000          | 2.4                | 2.4              |
| Unionen                                | -               | 5,400,000          | 2.4                | 2.4              |
| CBNY-National Financial Services LL    | -               | 5,343,977          | 2.4                | 2.4              |
| <b>Total, 10 largest shareholders</b>  | <b>-</b>        | <b>77,602,395</b>  | <b>35.0</b>        | <b>34.6</b>      |
| <b>Summary, other</b>                  | <b>971,024</b>  | <b>143,467,124</b> | <b>65.0</b>        | <b>65.4</b>      |
| <b>Total</b>                           | <b>971,024</b>  | <b>221,069,519</b> | <b>100.0</b>       | <b>100.0</b>     |

|                                   |               |
|-----------------------------------|---------------|
| <b>Ticker symbol:</b>             | EPIS B        |
| <b>ISIN code AK A:</b>            | SE0003523869  |
| <b>ISIN code AK B:</b>            | SE0003491562  |
| <b>Order book ID:</b>             | 78,419        |
| <b>No. Of shares outstanding:</b> | 222,040,543   |
| <b>Quota value:</b>               | 0.3           |
| <b>Round lot:</b>                 | 1 share       |
| <b>Share capital:</b>             | 66,668,546.29 |

### Share issues and share conversions

#### Directed share issue during the first six months

During the first six months of 2020, Episurf Medical conducted a directed share issue. The directed share issue was aimed at a limited number of institutional investors, including the Fourth Swedish National Pension Fund, Nyenburgh Investment Partners, Rhenman Partners Asset Management, and Strand Kapitalförvaltning Fonder. The subscription price per share was SEK 1.50, and the company was allocated a total of SEK 90m before deduction for issue costs. Through the directed issue, the company's shares increased by 59,999,998 B-shares, and the company's share capital increased by SEK 18,015,235.69.

#### Rights issue during the first six months

During the first six months of 2020, Episurf Medical completed a rights issue with a subscription period from March 19 to April 2, 2020. The new B-shares were issued for SEK 1.50 per share. The company reported the outcome on April 7, 2020, and it showed that 13,884,906 shares corresponding to approximately 40.7 percent of the rights issue were subscribed for by the exercise of subscription rights (including subscription undertakings). In addition, 918,363 shares were subscribed without subscription rights, corresponding to approximately 2.7 percent of the rights issue. 19,295,764 shares, corresponding to approximately 56.5 percent of the issue, were subscribed for by guarantors. Through the rights issue, Episurf Medical received approximately SEK 51m before the deduction of costs related to the rights issue. Through the rights issue, the company's shares increased by 34,099,033 B-shares, and the company's share capital increased by SEK 10,238,368.77.

#### Directed share issue during the fourth quarter

During the fourth quarter, Episurf Medical conducted a directed share issue. The directed share issue was aimed at a limited number of strategic and institutional investors, including the Second Swedish National Pension Fund, the Fourth Swedish National Pension Fund, Nyenburgh Holding, Primas Invest, Rhenman & Partners, Strand Kapitalförvaltning, the Third Swedish National Pension Fund, and Unionen. The subscription price per share was SEK 1.80, and the company was allocated a total of SEK 66m before deduction for issue costs. Through the directed issue, the company's shares increased by 36,811,000 B-shares, and the company's share capital increased by SEK 11,052,647.52.

### Warrants

During the period a number of warrants were issued to employees within the group.

### Share price performance and trading

Episurf Medical's share price at year-end was SEK 3.03 (1.17), which is equal to a market capitalisation, calculated on the total number of class A and B shares, of SEK 672.8 million (106.4). During the financial year, the share price changed by 159 percent (-59.7). The highest price paid during the year was SEK 3.225 (2.95) and the lowest was SEK 1.00 (0.94). During the year, 348,755,622 (112,851,979) class B shares were traded on Nasdaq Stockholm for a total value of SEK 678.0 million (156.2).

### Ownership structure

The number of shareholders at year-end was 9,544 (5,273). The ten largest shareholders in Episurf Medical in terms of voting power held shares corresponding to 35.0 percent (36.4) of the share capital and 34.6 percent (37.2) of the votes. The largest shareholder, Skandinaviska Enskilda Banken, W8IMY, held shares corresponding to 4.8 percent (10.6) of the share capital and 4.7 percent (10.4) of the votes.

#### Ownership structure by size of holding at 31 December 2020

| Holding       | No. Of shareholders | Class A shares | Class B shares     | % of capital  | % of votes     | Market value (SEK 000s) |
|---------------|---------------------|----------------|--------------------|---------------|----------------|-------------------------|
| 1-500         | 3,545               | 2,283          | 551,829            | 0,25%         | 0,25%          | 1,672                   |
| 501-1.000     | 1,080               | 2,058          | 882,389            | 0,40%         | 0,40%          | 2,674                   |
| 1.001-5.000   | 2,395               | 15,080         | 6,355,223          | 2,87%         | 2,86%          | 19,256                  |
| 5.001-10.000  | 951                 | 29,192         | 7,324,53           | 3,31%         | 3,31%          | 22,193                  |
| 10.001-15.000 | 351                 | -              | 4,413,240          | 1,99%         | 1,97%          | 13,372                  |
| 15.001-20.000 | 242                 | -              | 4,465,337          | 2,01%         | 1,99%          | 13,530                  |
| 20.001 -      | 980                 | 922,411        | 197,076,964        | 89,17%        | 89,22%         | 597,143                 |
| <b>Total</b>  | <b>9,544</b>        | <b>971,024</b> | <b>221,069,519</b> | <b>100,00</b> | <b>100,00%</b> | <b>669,841</b>          |

#### Development of the share

| Year | Event                               | Quota value | Increase in the no. Of shares | Increase in the share capital | Total no. Of shares | Total share capital |
|------|-------------------------------------|-------------|-------------------------------|-------------------------------|---------------------|---------------------|
| 2008 | Company formed                      | 0.01        | 10,000,000                    | 100,000                       | 10,000,000          | 100,000             |
| 2010 | New share issue                     | 0.01        | 800,000                       | 8,000                         | 10,800,000          | 108,000             |
| 2010 | Bonus issue                         | 0.05        | -                             | 432,000                       | 10,800,000          | 540,000             |
| 2010 | New share issue                     | 0.05        | 2,000,000                     | 100,000                       | 12,800,000          | 640,000             |
| 2011 | New share issue                     | 0.05        | 25,600,000                    | 1,280,000                     | 38,400,000          | 1,920,000           |
| 2011 | Merge                               | 0.30        | 1:6                           | -                             | 6,400,000           | 1,920,000           |
| 2013 | New share issue                     | 0.30        | 1,553,986                     | 446,196                       | 7,953,986           | 2,386,196           |
| 2014 | New share issue                     | 0.30        | 2,593                         | 778                           | 7,956,579           | 2,386,974           |
| 2015 | New share issue                     | 0.30        | 8,006,726                     | 2,402,017                     | 15,963,305          | 4,788,991           |
| 2016 | Reduction by cancellation of shares | 0.30        | 13,501                        | -                             | 15,949,804          | 4,784,941           |
| 2016 | Bonus issue                         | 0.30        | -                             | 4,050                         | 15,949,804          | 4,788,992           |
| 2017 | New share issue                     | 0.30        | 14,599,691                    | 4,383,614                     | 30,549,495          | 9,172,606           |
| 2018 | Conversion convertibles             | 0.30        | 1,081,674                     | 324,777                       | 31,631,169          | 9,497,383           |
| 2018 | New share issue*                    | 0.30        | 3,290,210                     | 987,898                       | 34,921,379          | 10,485,281          |
| 2019 | Conversion convertibles             | 0.30        | 4,339,166                     | 684,358                       | 37,200,642          | 11,169,639          |
| 2019 | New share issue                     | 0.30        | 53,730,113                    | 16,132,678                    | 90,930,755          | 27,302,317          |
| 2020 | Directed share issue                | 0.30        | 59,999,999                    | 18,015,236                    | 150,930,754         | 45,317,552          |
| 2020 | Rights issue                        | 0.30        | 34,099,033                    | 10,238,369                    | 185,029,787         | 55,555,921          |
| 2020 | Directed share issue                | 0.30        | 36,811,000                    | 11,052,648                    | 221,840,787         | 66,608,569          |
| 2020 | Conversion warrants                 | 0.30        | 199,756                       | 59,978                        | 222,040,543         | 66,668,546          |

\*The Swedish Companies Registration Office registered the share issue January 9. 2019

## Administration report

The Board of Directors and the CEO of Episurf Medical AB (publ), corporate identification number 556767-0541, hereby present the annual report for the financial year from 1 January 2020 to 31 December 2020.

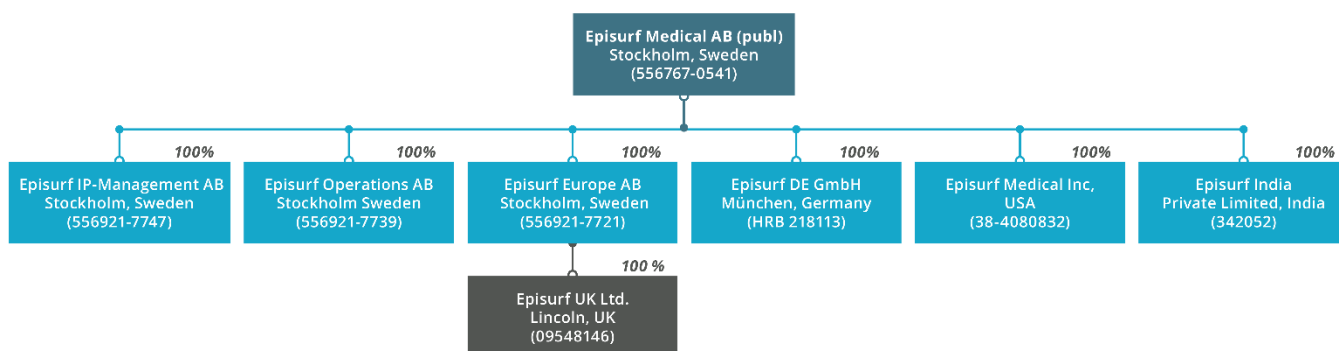
### Group structure

The structure of the Group is described in the figure below, setting forth the ownership of the subsidiaries, including information on the Group Companies' name, corporate identification number and registered office.

### General information about operations

Episurf Medical, is a medical technology company that develops and commercialises patient-specific products for the treatment of painful joint injuries. By combining expertise in implant development with patented technology for customised design and production, Episurf Medical can manufacture perfectly adapted implants based on each individual patient's unique anatomy and injury and thereby give people with painful joint injuries a more active and healthy life. Episurf Medical is headquartered in Stockholm and has an in-house sales organisation in Europe.

## Group structure



### Product portfolio

Episurf Medical has developed a platform for the design and manufacture of patient-specific implants (Episealer®) and surgical tools (including the patient-specific drill guide (Epiguide®) for the treatment of painful joints. The Episealer® implants are primarily intended for patients in the age category of 30–65 years with focal cartilage and bone defects of the knee and ankle joint of traumatic or degenerative origin, and are aimed at bridging the gap between conservative treatment methods, early stage biological surgical procedures and knee replacement surgery. The scalable µFidelity® system is a proprietary web-based ordering system developed for surgical pre-planning and cost-effective patient customisation. The system is the first in the world to enable large-scale precision-engineered production of patient-specific resurfacing implants and surgical tools.

Episurf Medical's first implant products, Episealer® Condyle Solo, Episealer® Trochlea Solo and Episealer® Femoral Twin received CE mark approval in 2013, 2014 and 2015, respectively. The Episealer® implants are the world's first patient-specific resurfacing implants for treatment of cartilage damage in the knee joint. This is just the beginning of what Episurf Medical can do with its technology. After that the company has received CE-mark approval for Epioscopy® Damage Assessment Tool, Episealer® Talus and Talus Osteotomy Guide.

### Research and development

Costs for development have during the year been capitalised with SEK 1.1m (1.1). Episurf Medical's product development is conducted according to a proven model that has been well-tried at the company since the first commercial product, the Episealer® Condyle Solo. Leading orthopaedic surgeons and researchers are engaged at an early stage of the development to identify clinical needs and patient benefits. Throughout the development process, the company maintains a close dialogue with involved clinics and orthopaedic surgeons, which facilitates rapid feedback and product adaptation. Furthermore, Episurf Medical has chosen to use certified materials in its products, which significantly reduces the development risks and development times. Episurf Medical is certified according to ISO13485:2016 with a medical device quality management system. All research and development is performed in alignment with that standard.

### Production

Episurf Medical's strategy is to use contract manufacturers for all production. External contract manufacturers provide scalability and full control over the manufacturing process while at the same time reducing the risk that growth opportunities will be limited by insufficient production capacity. However, all patient-specific design is carried out in-house.

The development of an efficient and cost-effective manufacturing process is a time-consuming process and is being carried out parallel to product development and the initial market launch of a product.

### **Market introduction**

When Episurf Medical's products were granted European market approval in the form of a CE mark, they were, as a first step, introduced to selected leading clinics and surgeons primarily in Northern and Central Europe, in which treated patients were followed up clinically. This so-called prelaunch is ongoing during a certain time, which can vary from country to country. The products will then be introduced to clinics and surgeons throughout Europe through a gradually expanded market launch.

Episurf Medical intends to drive sales in the largest European markets under its own management. The company's primary markets in 2021 will continue to be Germany, the UK, the Nordic countries and Benelux. In addition, preparations are underway for the launch of a knee product portfolio in North America. The launch in North America may be carried out together with a partner. Further, the company is in the early stages of opening up distribution markets in primarily the Middle East and Asia.

### **Significant events during the financial year**

- » Episurf Medical conducted a directed share issue and fully guaranteed rights issue of in total SEK 140m prior to transaction costs
- » Episurf Medical received CE mark for Episealer® Talus and Talus Osteotomy Guide
- » Episurf Medical updated on AI-based production process
- » Episurf Medical reached milestone of 700 implants
- » Episurf Medical announced that the first surgery in Italy has been scheduled
- » Episealer® was presented at a sports medicine meeting in Germany
- » Clinical data for Episealer® were presented at orthopaedic congress in The United Kingdom
- » Important European patent approval received for Episurf Medical within 3D visualisation
- » Episurf Medical announced positive results from a clinical study with follow-up of the 30 first Swedish patients
- » Episurf Medical announced progress for European sites in the US clinical trial, the EPIC-Knee study
- » Episurf Medical announced positive results from the first comparative Episealer® study
- » US patent approvals for Episurf Medical
- » Episealer® Talus was registered for sale in Italy and Spain
- » Episurf Medical announced that results from Episealer Knee® multicenter study have been submitted
- » Episurf Medical has received patent approvals in Europe, Korea, Japan
- » Episurf Medical announced that the first surgery in the Asia-Pacific region has been scheduled
- » Episurf Medical announced that enrolment of patients has been initiated in North America and Europe in Episurf Medical's IDE clinical trial
- » Results from Swedish multi-centre clinical trial with follow-up of 30 Episealer® patients was accepted for scientific publication
- » Results from European multicenter study with follow-up of 80 Episealer® patients was accepted for scientific publication
- » Episurf Medical provided long-term market share targets for the Episealer® knee technology in the initially prioritised markets
- » Episurf Medical became an approved supplier to BMI Healthcare, the largest hospital provider in the UK
- » Episurf Medical received patent approval in Europe
- » Episealer® implants were approved for sale in France
- » Episealer® surgery in France and Poland was scheduled, which constitute new markets for Episurf
- » First surgery was performed in Episurf Medical's IDE study for the Episealer® Knee implant
- » Episurf Medical reached a milestone of 800 approved implants
- » Episurf Medical carried out a directed share issue and raised SEK 66m
- » Episurf Medical entered into licensing agreement of SEK 1.5m for µiFidelity® software platform
- » Episurf Medical entered into a distribution agreement for France and additional markets in Asia
- » Episurf Medical entered into an advisory agreement with Prof. Doctor João Espregueira-Mendes regarding establishment of the Episealer® knee technology in India and Portugal
- » Data showing high implant survival rate for Episealer® were accepted for publication
- » The first Episealer® surgery was performed in the US, Asia and Scotland
- » First Episealer® Talus surgery in Scandinavia performed
- » Episurf Medical reached milestone of 900 approved implants

### **Significant events after the end of the financial year**

- » Episurf Medical announced its intention to file a 510(k) application in the US for an Episealer® Patellofemoral System

- » First Episealer® Talus surgery in the Asia-Pacific region performed
- » New patents approved in Hong Kong and US for Episurf Medical
- » Episurf Medical entered into distribution agreement for Australia and New Zealand
- » Episealer®: Clinical results with 5-years' follow-up data will be presented at the 3rd World Arthroplasty Congress
- » Clinical results for Episealer® were accepted for presentation at the 19<sup>th</sup> ESSKA congress
- » Episurf Medical provided COVID-19 related update ahead of an investor conference

### **Employees**

At 31 December 2020, the Group had 25 employees (25), of whom employees in the parent company Episurf Medical AB totaled to 13 (12). Personnel costs amounted to SEK 28.3m (28.1) in the Group and SEK 13.7m (12.6) in the parent company. For additional information about the average number of employees, salaries, other remuneration and social security expenses, see Note 9.

### **Environment, ethics and responsibility**

Episurf Medical is actively committed to corporate responsibility and sustainability. This commitment covers areas that are primarily related to ethical, environmental and occupational health issues, issues of a social nature and transparency to the shareholders.

Episurf Medical's contribution to society is to offer people with painful joint injuries a longer, more active and healthier life by providing effective, minimally invasive, patient-specific treatment alternatives.

Episurf Medical works in an industry where ethical and regulatory aspects are of major importance in shaping the company's operations. As a result, we continuously focus on these issues with the aim of consistently meeting the established requirements by a wide margin. As part of this work, Episurf Medical in 2015 implemented a quality management system according to ISO 13485, a standard for medical devices that specifies how these are to be developed and manufactured, for use in the healthcare sector. Episurf Medical's environmental policy is to include environmental consideration as a natural component of the company's operations. Episurf Medical has no in-house production, which means that its operations have a very limited direct impact on the environment and local community. Regarding production of Episurf Medical's products, the company's main suppliers have production facilities certified and meeting ethical, environmental and health and safety criteria. Being open and providing the shareholders and stakeholders with full transparency of the company are top priorities for Episurf Medical. Accordingly, updated and relevant information will always be available on the company's website under the tab "Investors". Here, stakeholders and shareholders can find clear, complete and reliable information to meet all of their needs, regardless of their level of expertise. Communication with the shareholders and stakeholders takes place via the website, newsletters and press releases. Through structured Board of Directors work, Episurf Medical ensures that corporate responsibility issues are addressed and included on the management's agenda.

### **Investments in the Group**

Group investments in intangible assets amounted to SEK 4.6m (5.5) for the financial year of which SEK 1.1m (1.1) are related to capitalised development costs, remaining investments relates to patents.

### **Investments in the parent company**

Investments in intangible assets, capitalised development costs, amounted to SEK 1.1m (1.1) for the financial year.

### **Consolidated income and expenses**

#### **Net sales and other operating income**

Consolidated net sales for the financial year from 1 January 2020 to 31 December 2020 amounted to SEK 5.0m (4.9). COVID-19 restrictions had a significant negative impact on the company's growth rate. During the year, the Group had a non-recurring income from a license agreement of SEK 1.5m for the µiFidelity® software platform.

#### **Expenses**

The Group's expenses for the financial year from 1 January 2020 to 31 December 2020 amounted to SEK 70.4m (74.2). The reduced costs are mainly due to cost savings in connection with COVID-19 and delayed costs regarding the EPIC-Knee study.

#### **Profit**

The consolidated operating loss for the financial year from 1 January 2020 to 31 December 2020 was SEK -63.4m (-68.9). The loss after financial items was SEK -63.9m (-69.8). The loss consists mainly of expenses for USA and development, marketing and sales activities related to the company's product launch.

### **Financial position and liquidity**

Consolidated cash and cash equivalents at year-end 2020 amounted to SEK 155.0m (25.3). Cash flow from operating activities before changes in working capital was SEK -54.3m (-61.7). Consolidated equity at year-end amounted to SEK 169.5m (41.4) and the equity ratio was 91.4 percent (71.9).

### **Parent company – Episurf Medical AB (publ)**

The parent company Episurf Medical AB (publ) conducts research, development and commercialisation of products for medical purposes. Net sales in the parent company for the financial year from 1 January 2020 to 31 December 2020 reached SEK 0.5m (0.6) and refers to intra-group revenues. During the year, the parent company have had a non-recurring income from a license agreement of SEK 1.5m for the µFidelity® software platform. Operating expenses amounted to SEK 38.9m (40.6). The reduced costs are mainly due to cost savings in connection with COVID-19 and delayed costs regarding the EPIC-Knee study. The operating loss was SEK -36.9m (-40.0) and the loss after financial items was SEK -36.8m (-40.9). The parent company's cash and cash equivalents at year end amounted to SEK 134.8m (18.1). Shares in Group companies amounted to SEK 162.9m (137.4), the increase is due to shareholder contributions made during the year. Long-term receivables from group companies amounted to SEK 33.2m (20.0), the increase is due to an increase in loan to group companies during the year.

### **Effects of the COVID-19 pandemic**

The outbreak of COVID-19 has affected people and companies all over the world, and Episurf closely monitors the development and effects of the pandemic as well as following the guidelines put forth by local authorities. The following paragraphs provide more detailed information on how the Group is affected by COVID-19.

### **Episealer® orders and revenue**

During the year, Episurf had higher net sales compared to 2019. Healthcare has focused on COVID-19 instead of elective surgery, which has affected Episurf's ability to grow during the year. Episurf's inflow of approved orders has been significantly affected during the financial year, but the exact impact is difficult to estimate. Episurf assesses that there will be a recovery in 2021. Episurf announced in March 2021 that Episurf had experienced double-digit growth in gross order intake in Q1 2021 compared to Q1 2020. Furthermore, the company has seen a 45% increase in the number of active customers during the quarter.

### **Government support/Organisation**

Episurf had executed short term layoffs in certain parts of the organisation during the financial year. The financial impact has been reported as it is deemed that all conditions have been met. The total amount stated in the income statement is SEK 0.5m during the financial year for the group. In addition to government grants, Episurf initiated cost-saving measures throughout the organisation.

### **Production**

Episurf has maintained an ongoing dialogue with our suppliers to avoid delays in deliveries, and up until this point in time, we haven't experienced any noticeable effects on our production process. Our assessment is that there will not be a significant impact during the first quarter 2021 either.

### **Clinical studies**

Episurf has had several studies published during the financial year, and the company assesses that other studies have been negatively impacted by COVID-19.

### **Geographic expansion**

Episurf's largest market continues to be Germany; however, during the financial year, the company carried out and planned operations in new countries such as Italy, France, Poland, and the US. The company assesses that expansion towards new countries may be somewhat delayed, but the company still has a good pace ahead.

### **Digitalisation**

Episurf continuously works to improve the digital environment, both internally and externally with our counterparts. Our assessment is that the COVID-19 pandemic has affected digitalisation in a positive direction and that this will have beneficial outcomes going forward.

## Five-year overview – Group

| mSEK                                         | Jan-Dec<br>2020 | Jan-Dec<br>2019 | Jan-Dec<br>2018 | Jan-Dec<br>2017 | Jan-Dec<br>2016 |
|----------------------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| <b>INCOME STATEMENT</b>                      |                 |                 |                 |                 |                 |
| Operating income                             | 7.0             | 5.4             | 4.3             | 3.1             | 2.7             |
| Operating expenses                           | -70.4           | -74.2           | -61.8           | -64.2           | -64.4           |
| <b>Operating loss</b>                        | <b>-63.4</b>    | <b>-68.9</b>    | <b>-57.5</b>    | <b>-61.2</b>    | <b>-61.7</b>    |
| Net interest income                          | -0.5            | -0.9            | -0.3            | 0.1             | 0.0             |
| <b>Loss before tax</b>                       | <b>-63.9</b>    | <b>-69.8</b>    | <b>-57.8</b>    | <b>-61.1</b>    | <b>-61.7</b>    |
| Income tax expense                           | 0.0             | 0.0             | -               | 0.0             | -               |
| <b>Loss for the year</b>                     | <b>-63.9</b>    | <b>-69.8</b>    | <b>-57.8</b>    | <b>-61.1</b>    | <b>-61.7</b>    |
| <b>ASSETS</b>                                |                 |                 |                 |                 |                 |
| Intangible assets                            | 20.8            | 21.5            | 21.1            | 16.0            | 12.6            |
| Equipment including rights-of-use assets     | 3.8             | 6.0             | 0.1             | 0.2             | 0.4             |
| Non-current financial assets                 | 0.5             | -               | -               | -               | -               |
| Other current assets                         | 5.3             | 4.9             | 5.3             | 5.7             | 5.0             |
| Cash                                         | 155.0           | 25.3            | 28.3            | 71.3            | 42.3            |
| <b>Total assets</b>                          | <b>185.4</b>    | <b>57.6</b>     | <b>54.8</b>     | <b>93.3</b>     | <b>60.3</b>     |
| <b>EQUITY AND LIABILITIES</b>                |                 |                 |                 |                 |                 |
| Equity                                       | 169.5           | 41.4            | 44.8            | 85.6            | 48.7            |
| Non-current liabilities                      | 2.1             | 3.5             | 0.0             | 0.0             | 0.0             |
| Current liabilities                          | 13.9            | 12.7            | 10.0            | 7.7             | 11.6            |
| <b>Total equity and liabilities</b>          | <b>185.4</b>    | <b>57.6</b>     | <b>54.8</b>     | <b>93.3</b>     | <b>60.3</b>     |
| mSEK                                         | Jan-Dec<br>2020 | Jan-Dec<br>2019 | Jan-Dec<br>2018 | Jan-Dec<br>2017 | Jan-Dec<br>2016 |
| <b>CASH FLOW STATEMENT</b>                   |                 |                 |                 |                 |                 |
| Cash flow from operating activities          | -54.1           | -59.2           | -52.3           | -61.4           | -56.1           |
| Cash flow from investing activities          | -5.1            | -5.5            | -9.7            | -7.5            | -5.6            |
| Cash flow from financing activities          | 188.8           | 61.6            | 19.1            | 97.8            | -               |
| <b>Cash flow for the year</b>                | <b>129.7</b>    | <b>-3.0</b>     | <b>-43.0</b>    | <b>29.0</b>     | <b>-61.7</b>    |
| <b>KEY RATIOS</b>                            |                 |                 |                 |                 |                 |
| Share price at year-end                      | 3.03            | 1.17            | 2.90            | 5.40            | 14.95           |
| Earnings per share (weighted average)        | -0.39           | -1.04           | -1.71           | -2.18           | -3.24           |
| Equity per share                             | 0.76            | 0.46            | 1.42            | 2.80            | 3.05            |
| Number of shares at end of year              | 222,040,543     | 90,930,755      | 31,631,169      | 30,549,495      | 15,949,804      |
| Average number of shares during the year     | 162,078,945     | 67,343,023      | 33,741,280      | 27,987,331      | 19,003,941      |
| Equity ratio, %                              | 91.4%           | 71.9%           | 81.8%           | 91.7%           | 80.8%           |
| Number of employees at the end of the year   | 25              | 25              | 24              | 26              | 27              |
| Cash and bank balances at the end of year    | 155.0           | 25.3            | 28.3            | 71.3            | 42.3            |
| Cash flow for the year                       | 129.7           | -3.0            | -43.0           | 29.0            | -61.7           |
| Investments in intangible assets             | 5.5             | 5.5             | 9.7             | 7.4             | 5.4             |
| Investments in property, plant and equipment | -               | -               | -               | 0.0             | 0.0             |

### Proposed appropriation of earnings

The Board of Directors proposes that the following earnings be at the disposal of the Annual General Meeting:

| SEK                      |                    |
|--------------------------|--------------------|
| Share premium reserve    | 546,227,299        |
| Accumulated deficit      | -250,350,376       |
| <b>Loss for the year</b> | <b>-36,814,808</b> |
| <b>Total</b>             | <b>259,062,115</b> |

The Board proposes that the earnings be appropriated so that SEK 259,062,115 is carried forward to new account, of which SEK 546,227,299 to the share premium reserve and SEK -287,165,184 to balanced earnings. Further information about the results of operations and financial positions of the Group and the parent company can be found in the following income statements, balance sheets, cash flow statements and additional note disclosures.

### Dividend

The Board of Directors and the CEO propose that no dividend be paid for the financial year from 1 January 2020 to 31 December 2020.

### The Group's future development and going concern

At the beginning of 2020, the company received, CE approval for the products Episealer® Talus and Talus Osteotomiguide. The have CE-mark for the products, the Epioscopy® Damage Assessment Tool, Episealer® Condyle Solo, Episealer® Trochlea Solo, and Episealer® Femoral Twin..

The introduction in Europe is planned to continue during 2021. In addition, market introduction will continue in selected markets in Asia and in the Middle East. The goals for 2021 are, among other things, continued commercialisation of the knee implants in the European market, continued development of clinical evidence during this commercialisation as well as additional surgeries with Episealer® Talus. Another high priority is the US strategy, where the patient recruitment to the FDA-approved IDE-study is a priority. At the same time, the company works with continued product development with a focus on Episurf Medical's unique digital 3D-based damage assessment tool (Epioscopy®) and other development projects to meet customer demands. During 2021, the company aims at submitting a so called 510(k) application to the US FDA for a new product, the Episealer® Patellofemoral System. Additional strengthening within the fields of health economic studies, regulatory affairs and reimbursement are also prioritised areas.

In Together, the board's opinion is to expect that it could boost profitability in a longer perspective and lead to increased sales revenues for the company in 2021. It will also mean that the activities surrounding the IDE-study will increase and thus also the company's costs. When the costs appear depends, in large, on the on the recruitment rate for patients.

As of December 31, 2020, the group had SEK 155.0m in cash and cash equivalents. During the year, the group has completed one rights issue and two directed issues and received a total of SEK 207m before issue costs.

During 2021, management estimate that expenses for market initiatives in the USA will result in increased expenses while costs in the European operations are at the same level as 2020.

### Financing Agreement

During 2018, a financing agreement with European Select Growth Opportunities Fund ("ESGOF") was entered into with Episurf Medical. The agreement provided the company with access to SEK 70m over a 36-month period in the form of convertible debt securities divided into a number of tranches. The Company used one tranche of SEK 7m and all convertible debentures have been converted. The Company announced in April 2019 that they intended to terminate the agreement and, it has now been terminated. In connection with the used tranche of convertibles, warrants were also issued to ESGOF and existing shareholders.

#### Main characteristics of the warrants issued to ESGOF

- » ESGOF and existing shareholders received warrants without further remuneration.
- » The warrants have a term of five (5) years from the date of the registration of their issuance with the Swedish Companies Registration Office. Each warrant gives right to subscribe for one (1) new share (subject to standard adjustments in accordance with the terms and conditions of the warrants) in Episurf Medical at a fixed strike price representing a 120 % premium to the reference price on the date of the request from Episurf Medical to issue a tranche.

#### Use of convertibles and warrants

- » The first and only tranche was conducted in the second quarter of 2018 as a targeted issue of SEK 7m through the issuance of 140 convertibles of 573,770 associated warrants to ESGOF (In connection with the termination of the

agreement in 2019, 573,770 warrants were returned). In connection with this, 1,131,462 warrants were also issued to the shareholders. All warrants have a redeeming price of SEK 6.10. Which has been adjusted in connection with the rights issue that was carried out during the second quarter of 2019 to 1.40 according to current conditions. See table below for follow-up of number of outstanding and utilised convertibles and warrants.

#### **Convertibles**

| <b>Tranches</b> | <b>Amount before costs</b> | <b>Date</b> | <b>Number of notes</b> | <b>Number utilised</b> | <b>Number of outstanding notes</b> |
|-----------------|----------------------------|-------------|------------------------|------------------------|------------------------------------|
| KV1             | SEK 7m                     | 2018-05-23  | 140                    | 140                    | -                                  |

#### **Warrants**

| <b>Tranche</b> | <b>Registration date</b> | <b>Term to maturity</b> | <b>Strike price</b> | <b>Number of warrants outstanding</b> | <b>Number of utilised</b> | <b>Number outstanding</b> |
|----------------|--------------------------|-------------------------|---------------------|---------------------------------------|---------------------------|---------------------------|
| KV1/TO4B       | 2018-05-23               | 5 year                  | 1,40*               | 1,705,232                             | 199,756                   | 1,505,476                 |

\* Has been adjusted based on calculation in the terms and conditions of the warrants in connection with the rights issue during the second quarter 2019, the rights issue 2020 does not entail any adjustments.

#### **Guidelines for remuneration to senior executives**

##### **Remuneration**

The annual general meeting held on 2 April 2020 resolved on the following guidelines for remuneration to the executives of Episurf Medical for the period until the annual general meeting of 2021.

Compensation and conditions of employment for the senior executive, by which is meant the CEO, the CFO, the COO, Sales director and Marketing director. December 31, 2020 is designed to ensure the company's access to executives with the right set of skills.

The remuneration consists of a fixed salary, a possible variable compensation, an incentive programme and other possible benefits including a company car and pension. The remuneration is on market terms and competitive, and is related to the senior executive's responsibilities and authorities. Any variable remuneration is related to established and well-defined objectives and to the fixed salary and it shall be limited to a maximum amount equivalent to six month's salary (gross).

The Board of directors is given the possibility to deviate from the above guidelines in individual cases should special reasons justify this, If this is the case, the information and the reasons for the deviation shall be reported at the next annual general meeting.

The proposed guidelines for remuneration to Group Management Team in 2021 that will be presented by the Board to the AGM on 10 May 2021 for approval are identical to the current guidelines. During the financial year 2020, the company's CEO Pål Ryfors has received a total amount of SEK 3.5m in remuneration.

#### **Current employment agreements for the CEO and senior executives**

##### **Remuneration and pension terms**

Remuneration and benefits for the senior executives are prepared by the remuneration committee and decided by the Board of directors.

##### **Termination of employment and severance pay**

A mutual notice period of six months applies for the termination of employment of CEO, Pål Ryfors, and a mutual notice period of three months applies for the termination of employment of the CFO, Veronica Wallin, the COO, Katarina Flodström and the Marketing Director, Fredrik Zetterberg. The CEO, Pål Ryfors is entitled to six months' severance pay. The COO, CFO, Chief Regulatory Officer, the Marketing Director and the Sales Director, are not entitled to any severance pay.

##### **Incentive programmes**

See more information about Episurf Medicals incentive programmes in note 9.

##### **Related party transactions**

Shareholder and Board member Leif Ryd has received consulting fees for ongoing work as well as work for the Clinical Advisory Board during the financial year of SEK 0.6m (0.6). Board member Wilder Fulford has received consulting fees for ongoing project during the financial year of SEK 0.7 (0.4).

The Chairman of the Board, Dennis Stripe receive SEK 0.4m, Wilder Fulford, Laura Shunk and Christian Krüeger receive remuneration of SEK 0.2m, Leif Ryd receive remuneration of SEK 0.1m. In total, the board fees amount to SEK 1.1m (1.1) in 2020.

### **Significant risks and uncertainties**

*The risk factors and critical circumstances that are considered significant for Episurf Medical and its Group's operations and future development are described below.*

#### **Covid-19 pandemic/pandemics**

Pandemics could affect Episurf and its sales in the future if healthcare pauses elective surgery. It is difficult for Episurf to assess and predict the company's impact, but future pandemics could significantly negatively impact the Group's operations, earnings, and financial position.

#### **Clinical trials**

Episurf Medical's products are used for ongoing clinical trials in humans and further clinical trials are planned. Clinical studies are of great importance in the area of repair of cartilage damages in joints. The collaboration with different surgeons and clinics is very important for Episurf Medical's operations. The results from clinical trials are, for example, the basis of regulatory approvals for the company's products in various markets. Additionally, the results are essential in the company's work of introducing products for surgeons, which in turn is important in order to receive market acceptance for Episurf Medical's products. Negative, unclear or insufficient results of a clinical trial may increase the risk of the company not being able to obtain necessary regulatory approvals and it may also make it difficult for the company to market the products. It is therefore difficult to evaluate and predict the time and cost aspects as well as the sales potential of the company's products. If a clinical trial performed by the company would result in unexpected or negative results, it may have a materially negative impact on the Group's operations, earnings and financial position.

#### **Dependence on reimbursement systems**

The company and its business partners' ability to successfully commercialise products and the prospect of potential future sales is dependent on, among other things, the level of reimbursement which the hospitals may receive for the company's products from insurance companies, public authorities and other buyers of medical products and services. These reimbursement systems are complicated and changing and it is, as a general rule, the purchasers' ambition to regulate the price of the company's products. In addition, the way in which a product is classified internally at a purchaser is often decisive for the level of reimbursement given for a product. There is a risk that the company's methods and products will not achieve or maintain the requirements of national reimbursement systems in different markets in which the company operates. Further, there is a risk that sufficiently favorable reimbursement from national reimbursement systems is not obtained and that national reimbursement systems will not pay any such compensation within a certain time period. There is also a risk that the company's products and methods do not get clinical acceptance or are not introduced in accordance with national clinical guidelines. If the company's products do not receive compensation in some markets from the national insurance systems and no clinical acceptance of the methods is received, it may have a materially adverse effect on future sales growth and thereby also on the Group's operations, earnings and financial position.

#### **Regulatory approval**

In order to market and sell medical devices, permits and approvals from, and registration with, relevant public authorities are required on each respective market. There is risk that Episurf Medical will not be able to obtain such permissions and approvals to the extent required to achieve a profitable business or achieve other future objectives. There is also a risk that the company will get permissions and approvals, but that it will take much longer time than expected to achieve that. Changes or amendments in the current regulations or classifications, political decisions or changed practices amongst the public authorities, insurance companies and other decision makers may lead to that Episurf Medical's current and future products will not be approved for specific markets, which may have a materially adverse effect on the Group's operations, earnings and financial position.

#### **Risks related to possible future revenue**

Episurf Medical's earnings are, among other things, dependent on Episurf Medical's ability to enter into further agreements for the distribution of the company's products. The opportunities to enter into such agreements are, among other things, dependent on Episurf Medical's credibility as a potential business partner and the quality of the company's products. There is a risk that such agreements cannot be entered into, or only entered into on terms which are considered to be unfavorable for the company. In order to enter into such agreements, potential distributors on different markets as well as other business partners may, especially as regards research and development, require that additional studies are conducted on Episurf Medical's products, which could result in delays and increased costs for the company. If Episurf Medical is unable

to enter into such agreements on terms favorable for the company, if such contracts lead to delays or increased costs, or if payments under such agreements are delayed or defaulted, it may have a materially adverse effect on the Group's operations, earnings and financial position. Episurf Medical's earnings are furthermore dependent on the company being successful in establishing its in-house sales organisation with direct sales, initially, in the Nordic countries, Germany and the United Kingdom. Should Episurf Medical not successfully succeed to establish new sales organisations or maintain or develop its current sales organisation and its relationship with customers, the company may not make any sales revenues which may have a materially negative impact on the Group's operations, earnings and financial position. There is also a risk that the processes for maintenance and development of the sales organisation becomes more time consuming and costly than Episurf Medical has estimated, which may have a material adverse effect on the Group's operations, earnings and financial position.

### **Market acceptance**

Episurf Medical operates in a competitive industry and many other companies are conducting research and development of medical devices, including research and development of such products that may, or in the future may, compete with the company's products or product candidates. Furthermore, research and development of products that does not directly compete with the company's products may replace parts of or the entire company's product portfolio on the market, which consequently may result in a decrease in demand for Episurf Medical's products.

Furthermore, Episurf Medical operates on a market in which its competitors have substantially greater financial resources than the company. If other competitive businesses develop products that directly or indirectly competes with the company's current and future products or develops products that wholly or partly may replace the company's product portfolio, or if the company otherwise fails to address the current and future competition on the market, it may have a materially negative impact on the Group's operations, earnings and financial position.

Furthermore, the company's products comprise new technology that has not previously been used for the intended uses. The company's products must also compete with more established treatments that currently are accepted as established practice. Thus, the ability of the company's products to compete is dependent on changes in established practice in the medical profession. Episurf Medical's ability to gain acceptance for its products in the medical profession and on the market is, among other things, dependent on the outcome of the currently on-going product launches. Furthermore, negative events during the controlled launches or elsewhere may occur because of Episurf Medical's products or an improper handling of Episurf Medical's products, which may affect the market acceptance in a negative way. If the company does not obtain a sufficient level of market acceptance and therefore cannot compete on the market effectively, it may have a materially adverse effect on the Group's operations, earnings and financial position.

### **Patient damages**

Patients taking part in the clinical trials and the controlled product launches conducted by the company may be negatively affected by the company's products or negatively affected due to an improper use of the company's products. If such negative effects would occur, the market access of the company's products and future product development may be delayed or stopped. Such negative effects may also lead to the company being liable for damages or subject to other claims, which may have a materially adverse effect on the Group's operations, earnings and financial position.

### **Complex and changing requirements**

Episurf's activities are regulated by laws and regulations, as well as by internal and external regulations, including regulations issued by the US FDA (Food and Drug Administration), ISO13485: 2016 certification and European Parliament and Council Regulation (EU) 2017/745 on Medical Devices ("MDR"). On 5 April 2017, the MDR was adopted to replace Council Directive 93/42 / EEC on medical devices ("MDD"). MDR is directly applicable without any implementation measures in the EU member states and replaces MDD after, as initially stated, a three-year transitional period. According to Article 123 of the MDR, the regulation applies from 26 May 2020. However, due to the COVID-19 pandemic in 2020, the transition period was prolonged to 26 May 2021. In general, the MDR means that the current system is being modernised through a number of initiatives, including strengthening the criteria for the appearance and processes of review of accredited notified bodies, increased transparency through the establishment of a comprehensive EU database for medical devices and a system for product traceability, as well as reinforcement and monitoring of products placed on the market for manufacturers. The company evaluates MDR's potential impact. There is a risk that the implementation of MDR may result in increased costs, time and requirements that the company must meet in order to retain or introduce new products in the European market.

In order to market and sell medical devices, Episurf Medical, its business partners and subcontractors may be required to have or obtain relevant permissions from regulatory authorities for various markets. For example, this may be CE marking in Europe or FDA-approval for the American market. The regulations regarding, for instance, pre-clinical and clinical trials and marketing of Episurf Medical's product portfolio are complex and change over time. The company has occasionally been awarded development grants, and the receipt of further grants can be conditioned with certain

requirements. In addition, the company is subject to extensive legislation and administrative practices, and can also in the future be subject to further legislation and administrative practices, including legislation and administrative practices regarding public procurement. Changes in relevant legislation, other regulations or administrative practices may lead to increased costs or otherwise hamper Episurf Medical's product development. In addition, the company can also be subject to sanctions if the company does not comply with the aforementioned rules and regulations, If any of these risks would materialise, it could have a material adverse effect on the company's business, financial position and results of operations.

The complex and changing laws and regulations governing Episurf's operations mean that the company must have effective internal control. Such internal controls include, for example, managing and monitoring day-to-day operations so that they are conducted in accordance with applicable legislation and regulations, and to check the company's financial reporting to comply with applicable principles and provisions of applicable accounting legislation, verify that the company has appropriate accounting systems for its administration and other activities, and make sure that the Company uses external expertise to support these measures. Errors, failures or inefficiencies in Episurf's internal control may result in the company's operations not being conducted in accordance with applicable laws and regulations, the company's accounting system failing to function properly or the company's operations cannot be adequately controlled. If any of the aforementioned risks were to be realised, it could have a material adverse effect on the group's operations, earnings and financial position.

### **IPR – Intellectual Property Protection**

Episurf Medical's future success will be dependent to a large extent on its ability to obtain and retain intellectual property protection, primarily patent protection, in the US, the EU, Asia and other areas and countries for the intellectual property rights that are attributable to the current and future products that are included in the company's portfolio. The scope for obtaining patent protection for innovations in the area of medical devices is generally difficult to assess and includes issues of a complex legal and scientific nature. Episurf Medical may not obtain patents for its products or its technology, and the patents also have a limited lifespan. Thus, there is a risk that Episurf Medical will not obtain patent protection for all its developed products or technologies, which can have a materially adverse effect on the Group's business, earnings and financial position.

In addition, there is a risk that the company's current and future patent portfolio and other intellectual property rights will not provide adequate commercial protection. The technology Episurf Medical is using during its research or in the medicinal devices Episurf Medical is developing and commercialising or intends to develop and commercialise may be infringing on patents that are owned or controlled by others. In addition, a third party may have a pending patent application that covers the same technology or products that the company is currently using or developing. There is a risk that the measures the company is taking, to protect such intellectual property rights, are not sufficient. In addition, there is always a risk that competitors and other parties, intentionally or unintentionally, infringe the company's intellectual property rights. Consequently, there is a risk that Episurf Medical may be viewed as an infringer of a third party intellectual property right, and that third parties may infringe Episurf Medical's intellectual property rights, which may have a materially adverse effect on the Group's business, earnings and financial position. Should Episurf Medical need to initiate legal proceedings in order to determine who holds the commercial rights for such innovations the cost for such proceeding may be substantial. The company may lose such proceeding, which could lead to Episurf Medical losing the protection of, or the right to sell any or all of the company's products. Episurf Medical may also have to pay substantial damages should Episurf Medical loose such legal proceedings.

Furthermore, there is a risk that the Group may become involved in disputes in court or with authorities in the context of Episurf Medical's business. Episurf Medical may for example be subject to claims relating to intellectual property rights, patient injuries or misleading and unfair marketing. Such processes may be time consuming, involve large amounts of money and may, regardless of the outcome, cause significant costs to the company, which may have a materially adverse effect on the Group's business, earnings and financial position.

### **Collaboration partners**

Episurf Medical is a small organisation and the company is therefore collaborating with a number of different business partners in order to maintain a high level of flexibility as well as access to the needed expertise and competence. Episurf Medical is dependent on a continued close collaboration with existing and future business partners such as researchers, technical consultants, distributors, leaders of clinical trials and subcontractors as regards production. There is a risk that existing and future business partners will not fulfil their obligations or that business partners with the right expertise and competence will not be available, which may result in delays or hamper the development of the products. The company's products are personalised and made to order for each specific surgery. In the case that the company fails to deliver the products in time, the surgeries may need to be rescheduled or cancelled, which may, among other things, damage the company's reputation and lead to claims for damages. Repeated failure to deliver products in time, irrespective if this is due to the company, its business partners or subcontractors, may have a materially adverse effect on the Group's operations, earnings and financial position.

Episurf Medical's business is dependent on that continuous research is performed in order to develop new products and improve the company's already existing products. There is a risk that the current business partners will decide to suspend cooperation with the company which may delay or hinder the development of the company's products. If delays occur of the company's research and development work it may in turn lead to delays in the launch of the company's future products, which may have a materially adverse effect on the Group's business, earnings and financial position.

#### **Key employees**

Episurf Medical's operations are highly dependent on a number of key employees, as these individuals together have industry-specific knowledge that is important to Episurf Medical. If any of these key employees would leave the company, it may delay or hamper the company's continued research, development and operations. The company is also dependent on being able to recruit and maintain qualified employees. There is strong competition for experienced personnel in the company's area of business and many of Episurf Medical's competitors have substantially greater financial resources than the company, which may lead to that the required personnel cannot be recruited or only recruited on terms unfavorable for the company. If the company does not succeed in recruiting or maintaining key personnel or other qualified personnel to the extent and under the conditions that are needed, it may have a materially adverse effect on the Group's operations, earnings and financial position. In addition, there is a risk that the board of directors, the senior executives or any key personnel may adversely affect the company by making erroneous decisions, which may have a materially adverse effect on the Group's business, earnings and financial position.

#### **Financial risks**

Episurf Medical is exposed to different types of financial risks such as market, liquidity, currency and credit risks. The market risks mainly comprise of interest rate risk and currency risk. The Group is exposed to foreign exchange risk arising from exposures to different currencies, primarily relating to transactions in the EU. The Board of Directors establishes the framework for exposure, management and monitoring of the financial risks and this framework is evaluated and revised yearly. The Board of Directors is authorised to decide on temporary deviations from the established framework. For further information, see Note 3.

#### **Share information**

Episurf Medical's shares are issued in two classes, class A and class B. Each class A share carries the right to three votes at a general meeting and each share of class B carries the right to one vote at a general meeting. Shares of class A can be freely converted to class B. As of 11 June 2014, the class B shares are traded on Nasdaq Stockholm with the ticker symbol EPIS B. Prior to this, the company's shares began trading on Nasdaq Stockholm First North on 15 August 2011.

At the beginning of the year the total number of shares in the company was 90,930,755 of which 971,024 were class A and 89,959,731 were class B shares. The total number of shares at year-end 2020 was 222,040,543 of which 971,024 were class A shares and 221,069,519 were class B shares. The total number of votes was 223,982,591.

The registered share capital at 31 December 2020 amounted to SEK 66,668,546.29 with a quota value of SEK 0.30 per share. According to the Articles of Association 31 December 2020, the share capital shall amount to no less than SEK 27,302,316.80 and no more than SEK 109,209,267.20, divided between no fewer than 90,930,755 shares and no more than 363,723,020 shares. The number of shareholders at year-end was 9,544 (5,273). The ten largest shareholders in Episurf Medical in terms of voting power held shares corresponding to 35.0 percent (36.4) of the share capital and 34.6 percent (37.2) of the votes. The largest shareholder, Skandinaviska Enskilda Banken, W8IMY, held shares corresponding to 4.8 percent (10.6) of the share capital and 4.7 percent (10.4) of the votes.

Episurf Medical AB is a Swedish public limited company that is domiciled in Stockholm. The share has been traded on Nasdaq Stockholm since 11 June 2014. In a limited company like Episurf Medical, governance, management and control are divided between the shareholders, the Board of Directors, the CEO and the executive management in accordance with the applicable laws, rules and instructions.

The diagram illustrates the corporate governance framework, centered around the **Board of Directors** (4). The framework includes the following components and their interactions:

- Shareholders** (1) elect the **AGM** (2) and the **Nominating committee** (3). Shareholders also provide **Votes** to the AGM.
- The **AGM** (2) elects the **Board of Directors** (4).
- The **Nominating committee** (3) proposes the **Board of Directors** (4).
- The **Board of Directors** (4) elects the **Auditors** (6) and the **Remuneration committee** (5).
- The **Auditors** (6) provide **Information Assurance** to the **Board of Directors** (4).
- The **Remuneration committee** (5) determines the **Remuneration structure** for the **President and CEO** (7).
- The **President and CEO** (7) oversees the **Executive management** (8).
- The **Executive management** (8) reports to the **Board of Directors** (4) on **Goals, Strategies, Policies, Governance instruments, Reports, and Internal control**.

**External steering instruments**  
Key external steering instruments that form the framework for corporate governance are:

- » The Swedish Companies Act
- » The Swedish Annual Accounts Act
- » Nasdaq Stockholm's rules
- » The Swedish Corporate Governance Code

**Internal steering instruments**  
Key internal binding control documents are:

- » The Articles of Association
- » The Board's procedural plan
- » Instructions for the CEO, audit committee, remuneration committee and financial reporting
- » Policies

Episurf Medical's Articles of Association can be downloaded from the company's website ([www.episurf.com](http://www.episurf.com)). Episurf Medical complies with the Code with effect from the listing on Nasdaq Stockholm's main market. The Code is based on the "comply or explain" principle. This means that a company that applies the Code may deviate from individual rules in the Code, but must explain the reasons for doing so. The Code must be applied in full in connection with the first annual general meeting after the year after listing.

## 1 Share and shareholders

The number of shareholders at year-end was 9,544 (5,273). The ten largest shareholders in Episurf Medical in terms of voting power held shares corresponding to 35.0 percent (36.4) of the share capital and 34.6 percent (37.2) of

the votes. The largest shareholder, Skandinaviska Enskilda Banken, W8IMY, held shares corresponding to 4.8 percent (10.6) of the share capital and 4.7 percent (10.4) of the votes. For further information about the share, shareholders and ownership structure, see pages 29–31 of the annual report.

## 2 General meeting of shareholders

The general meeting of shareholders is the company's highest decision-making body and, according to the Articles of Association, shall be held yearly within six months after the end of the financial year. Shareholders who are recorded in the share register five days before the general meeting and who provide notification of attendance in the correct manner have the right to participate.

Notice of attendance shall be made to the company no later than the date stated in the notice of meeting. All shareholders who are recorded in the share register on the record date and who have given notice of their attendance on time have the right to attend the meeting and vote the total number of shares held. Notice of general meetings shall be given through an announcement in the Post- och Inrikes Tidningar (the Official Gazette) and through publication on the company's website. At the same time, an announcement that notice has been given shall be published in Dagens Industri and on the company's website ([www.episurf.com](http://www.episurf.com)).

At the Annual General Meeting (AGM), the shareholders elect the Board of Directors and, when appropriate, the auditors. The AGM also resolves on matters such as principles for appointment of the nominating committee, discharge from liability for the Board of Directors and the CEO, adoption of the annual report, appropriation of earnings, fees for the Board of Directors and auditors, and guidelines for remuneration to the CEO and other senior executives.

Notices, Minutes, communiqués and other materials related to general meetings are published on the company's website.

It is the General meeting which decides on amendment of the Article of Association.

### AGM 2020

#### The AGM on 2 April 2020 passed the following resolutions:

- » To adopt the income statement and balance sheet.
- » To appropriate the earnings according to the Board's proposal in the annual report.
- » To grant the Board of Directors and the CEO discharge from liability for the past financial year.
- » The Board of Directors shall comprise of five ordinary members with no deputy members.
- » To pay a fixed board fee of SEK 200.000 to each member of the Board, however that Leif Ryd, shall receive an annual fee of SEK 100.000 and the Chairman of the Board of Directors shall receive an annual fee of SEK 400.000. the total is therefore SEK 1.100.000. No fees paid for work on the Board's committees. It was proposed that fees for the auditors be paid according to approved account.
- » To re-elect Laura Shunk, Leif Ryd, Christian Krüeger, Dennis Stripe and Wilder Fulford as members of the Board of Directors for the period until the end of next annual general meeting. It was further resolved to re-elect Dennis Stripe as chairman of the Board of Directors.
- » To re-elect the authorised public accounting firm KPMG AB as the company's auditor for the period until the end of the next annual general meeting, with Duane Swanson as auditor-in-charge.
- » To Adopt the procedures for establishing the nomination committee for the 2021 annual general meeting in accordance with the proposal of the nomination committee.
- » To adopt the guidelines for remuneration to the senior management in accordance with the proposal of the Board of Directors until the 2021 annual general meeting.
- » To (a) adopt an incentive programme, (b) issue warrants of series 2020/2023 (A), and (c) issue warrants of series 2020/2023 (B) and approve transfers of warrants of series 2020/2023(B).
- » To Authorise the Board of Directors to resolve on new issues of shares for the period until the 2021 annual general meeting.

### Extraordinary general meeting 2020

The extraordinary general meeting on 10 March 2020 resolved to approve the Board of Director's resolution regarding amendments to the articles of association and on a new issue of shares with preferential rights for shareholders.

### AGM 2021

The 2021 AGM will be held in Stockholm on 10 May 2021. The notice of meeting was made public through a press release and announcements in Post och Inrikes Tidningar and Dagens Industri, as well as published on Episurf Medical's website.

### 3 Nomination committee

Ahead of the AGM, the nominating committee shall put forward proposals for the number of Board members, the composition of the Board, fees to the Board of Directors, the Chairman of the AGM and of the Board, and when appropriate, proposals for election of an auditor and auditing fees. The 2020 AGM resolved on principles for Episurf Medical's nominating committee that shall apply until changed by a future general meeting, according to the following:

» The nominating committee shall have four members. The three largest shareholders in the company in terms of voting power in the company at 31 August the year before the year in which the AGM is held shall each have the right to appoint a member to the nominating committee. The Board Chairman shall also be appointed as a member of the nominating committee. The CEO and other members of the executive management shall not be members of the nominating committee.

#### **Members of the nomination Committee ahead of 2021 AGM**

**Dennis Stripe**, Chairman of Episurf Medical AB

**Leif Ryd**, Representing Niles Noblitt

**Robert Charpentier**, Representing Carl Palmstierna

**Max Mennfort**, Representing Pål Ryfors

Robert Charpentier has been appointed chairman of the Nomination Committee.

#### **The work of Nomination Committee**

» By 15 October, the Board Chairman shall convene the largest shareholders in the company. If any of these should waive its right to appoint a member to the nominating committee, the next largest shareholder in order of voting power shall be given the opportunity to appoint a member.

» The composition of the nominating committee shall be made public no later than six months before the AGM.

» The Board Chairman shall convene the first meeting of the nominating committee. However, the Board Chairman shall not be appointed as chairman of the nominating committee.

» If it becomes known that any of the shareholders that have appointed a member to the nominating committee is no longer one of the largest shareholders, due to changes in the shareholder's holding or as a result of changes in other shareholders' holdings, the member appointed by the shareholder, if the nominating committee deems it appropriate, shall resign and be replaced by a new member who is appointed by the shareholder which at that time is the largest registered shareholder that has not already appointed a member to the nominating committee. If the registered ownership conditions are otherwise significantly changed before the nominating committee has completed its work, and if the nominating committee deems it appropriate, the composition of the nominating committee shall be changed according to the above principles.

» The nominating committee's mandate period extends until a new nominating committee has been appointed.

» The Chairman of the Board shall annually present an evaluation of the Board's work during the year for the nominating committee, which should be the base for the work for the Nomination committee together with the requirements of the Swedish code and specific requirements of Episurf Medical AB. The nominating committee's proposals are published in the notice of the AGM, on the company's website and at the AGM.

#### **Nomination Committee meetings**

Nomination committee for the AGM 2021 has held one formal meeting in addition to the continuous discussions. No fees have been paid for work on the nominating committee.

### 4 Board of Directors

Episurf Medical's Board of Directors consists of five members elected by the AGM, with no deputies. The members of the Board are elected by the AGM to serve for the period until the company's next AGM. The 2020 AGM elected the Board according to the table below, which also shows fees, independence, etc. According to the Articles of Association, the Board shall consist of at least three and at most eight members. The CEO is not a member of the Board.

#### **Independent**

The company's Board of Directors has been assessed to meet the independence requirements, as four of the five members elected by the AGM are independent in relation to the company and its management and five of the five members are independent in relation to major shareholders. Leif Ryd is not deemed to be independent in relation to the company and its management as he currently active as a consultant in the company. One Board member is a woman, but in accordance with the Code. the Board intends to strive for a more even gender distribution on the Board.

### The Board's work and responsibilities

The Board of Directors establishes the company's goals, strategies, budget and business plan. The Board is responsible for the company's organisation and administration and for ensuring the quality of its financial reporting and internal control. Furthermore, the Board shall examine and approve the financial reports and establish significant policies and regulatory systems. The Board shall also resolve on decisions outside the scope of day-to-day management, such as major investments and changes. The Board shall monitor the company's operations based on the established goals and guidelines. This work is governed by the Swedish Companies Act, the Articles of Association, the Code and the Board's procedural plan.

Every year, the Board shall hold an inaugural meeting immediately following the AGM. The inaugural meeting shall among other things appoint the company's authorised signatories and shall review and adopt the Board's procedural plan. The company's Board meetings shall normally deal with the company's financial situation and matters of material importance to the company. The CEO reports continuously on business plans and strategic issues. According to the Board's procedural plan, the Board is a quorum when at least three of its members are present.

### Composition of the Board

| Name              | Function       | Born in | Elected in | Fees<br>(SEKm) | Meeting<br>attendance | Independent         |                      |
|-------------------|----------------|---------|------------|----------------|-----------------------|---------------------|----------------------|
|                   |                |         |            |                |                       | From the<br>company | From<br>shareholders |
| Dennis Stripe     | Board Chairman | 1957    | 2016       | 0.4            | 17/17                 | Yes                 | Yes                  |
| Christian Krüeger | Board Member   | 1966    | 2016       | 0.2            | 17/17                 | Yes                 | Yes                  |
| Laura Shunk       | Board Member   | 1957    | 2017       | 0.2            | 17/17                 | Yes                 | Yes                  |
| Leif Ryd          | Board Member   | 1949    | 2009       | 0.1            | 17/17                 | No                  | Yes                  |
| Wilder Fulford    | Board Member   | 1958    | 2016       | 0.2            | 17/17                 | Yes                 | Yes                  |

Pursuant to the Swedish Companies Act, Episurf Medical's Board of Directors has adopted a written procedural plan for its work. The now applicable procedural plan and CEO instructions were adopted at the inaugural Board meeting no 11, on 18 June 2020. The procedural plan among other things regulates how the Board shall conduct its work and which matters are to be dealt with by the Board. The procedural plan also regulates how the Board is to be continuously provided with information and financial reporting by the CEO.

The Board in its entirety takes part in matters related to auditing, including monitoring and evaluation of the audit process, quality assurance of the company's financial reporting assessment of reports from the independent auditor and review of the auditors' independence from the company, including the scope of any non-audit services provided by the auditor to the company. The Board has therefore not set up any audit committee.

The Board shall annually review the Board's and the CEO's work and present it to the Nomination Committee.

### Work of the Board in 2020

The Board held seventeen meetings in 2020. The Board members' attendance is shown in the table above. Each scheduled Board meeting followed an agenda and decision data was sent to the members of the Board ahead of each meeting. The CEO and certain other senior executives in the company have taken part in Board meetings in order to present reports. The Board has dealt with matters such as R&D, marketing plans and commercialisation of products, organisation, risk and internal control, financial reporting and monitoring, financial position and investments. In 2020 the Board devoted special attention to issues related to marketing, sales and financing.

Evaluation of the Board's work was conducted in November 2020 and was presented written to the Board and the Nomination Committee in November 2020 and then orally for the Board November 19, 2020. Evaluation of the Board's executive director Pål Ryfors, was conducted in November 2020.

### Remuneration to the Board

Fees and other remuneration to the members of the board of directors, including the Chairman, are determined by a general meeting of the shareholders of the company. At the annual general meeting held on 2 April 2020, it was resolved that remuneration shall be paid with SEK 0.4m to Dennis Stripe, who was appointed Chairman of the board of directors and SEK 0.2m to Wilder Fulford, Laura Shunk and Christian Krüeger and SEK 0.1m to Leif Ryd. It was further resolved that no remuneration shall be paid for committee work. During the financial year 2020, the total remuneration to the members of the board of directors amounted to SEK 1.1m distributed in accordance with the table above.

### BOARD COMMITTEES

#### 5 Remuneration committee

According to the Code, the members of the remuneration committee shall be independent in relation to the company and the senior executives.

The board of directors' remuneration committee continuously evaluates the remuneration to senior executives in view of current market conditions.

The Remuneration Committee currently consists of three members: Dennis Stripe, Christian Krüeger, Wilder Fulford, which are all considered to be independent in relation to the company and the senior executives. The remuneration committee's main tasks are to:

- (a) prepare the board of directors' decisions on issues relating to compensation and other employment terms for the senior executives,
- (b) monitor and to evaluate current remuneration structures, remuneration levels and programs for variable remuneration to the senior executives and
- (c) to monitor and evaluate the outcome of variable compensation schemes and the company's compliance with remuneration guidelines adopted by the general meeting.

After the annual meeting 2020, the Remuneration Committee held two meetings.

#### **Remuneration committee, no. of meetings**

Dennis Stripe 2/2

Christian Krüeger 2/2

Wilder Fulford 2/2

#### **– Audit Committee**

Episurf Medical deviates from the Code in that it has no specially appointed audit committee. Matters related to auditing are dealt with by the Board, pursuant to the Swedish Companies Act. Chapter 8. section 49 a. paragraph 2.

The Board's assessment is that Episurf Medical has no need for a separate audit committee in view of Episurf Medical's size and that audit-related matters are best handled by the entire Board.

## **6 Auditors**

The independent auditor is appointed at the AGM to examine the company's financial accounts and the administration of the company by the Board of Directors and the CEO.



#### **Auditor**

The 2020 AGM elected the auditing firm of KPMG AB as the company's independent auditor to serve until the end of the 2021 AGM. Auditor in Charge is Authorised Public Accountant Duane Swanson. Duane Swanson, born in 1959. is an Authorised Public Accountant and a member of FAR. KPMG AB's office address is: Vasagatan 16, 101 27 Stockholm, Sweden.

## **7-8 CEO and executive management**

The Board appoints the CEO. The CEO oversees the company's operations, supervises its day-to-day management and is responsible for ensuring that the Board is provided with the information necessary to discharge its duties.

The CEO is not a member of the Board. The CEO presents reports to the Board and takes part in meetings, except for when the CEO is evaluated, at which time the Board meets with the auditor without the presence of the executive management, or if the Board so decides. The segregation of responsibilities between the Board of Directors and the CEO is described in written CEO instructions that are subject to yearly revision.

The CEO appoints the members of the executive management. The role of the executive management is to drive business operations and monitor the company's development.

At the beginning of 2019 the executive management consisted of Pål Ryfors (CEO), Veronica Wallin (CFO), Katarina Flodström (COO), Fredrik Zetterberg (Marketing Director), Göran Martinsson (Sales Director).

On May 1, 2020, the company's sales director Göran Martinsson assumed a new role as head of distribution markets, and the company's CEO was also appointed acting sales director. In connection with the role changing, Göran Martinsson left the management team.

## Remuneration to the CEO and management

**THE COMPANY'S AGM ON 2 April 2020** resolved to implement the following guidelines for remuneration to senior executives for the period until the 2021 AGM.

Remuneration and terms of employment for senior executives, by which is meant the Chief Executive Officer, the Chief Financial Officer, the Chief Operating Officer, the Sales Director and the Marketing Director December 31, 2020, shall be designed to ensure the company's access to executives with the right expertise. This remuneration shall consist of basic salary, possible variable remuneration, incentive programs and other benefits including a company car and pension contributions. The remuneration shall be market-based and proportionate to the executive's powers and responsibilities. Any variable remuneration shall be related to established, well-defined targets and to the basic salary, and shall be limited to a maximum amount equal to six months' salary (gross).

Episurf Medical's pension policy is based on an individual occupational pension in a maximum amount equal to 30 percent of basic salary. The company has a term of notice of no more than six months. Other remuneration and benefits, such as company car, shall be market-based.

The Board is given the opportunity to deviate from the above guidelines in individual cases where there is special reason to do so. In such case, information and the reasons for the deviation shall be reported at the next AGM. Aside from the CEO, no other senior executive or other employee is entitled to termination benefits.

On 25 February 2015 the Board decided to appoint a remuneration committee and it currently consists of Dennis Stripe, who is also chairman of the committee, Wilder Fulford and Christian Krüeger.

Remuneration to other senior executives is negotiated with the CEO and must be approved by the Board Chairman.

### **Incentive programmes**

See more information about Episurf Medicals incentive programmes in note 9.

### **Proposal for the Annual General Meeting to be held on May 10, 2021**

The Board of Directors proposes that the Meeting resolves on the following guidelines for remuneration to senior executives. The guidelines comprise the CEO and the other members of the senior management of the company. Remuneration covered by the guidelines shall include salary and other remuneration to the senior executives. These guidelines shall not apply to any remuneration resolved upon or approved by the general meeting. Hence, these guidelines do not apply to share-based incentive programs or board fees to the Board members.

To the extent that a non-employed Board member elected by the general meeting performs work for the company, besides the Board assignment, consultancy fees and other remuneration on market terms may be granted for such work. Decisions on consultancy fees and other remuneration to non-employed Board members elected by the general meeting are taken by the Remuneration Committee.

For employments governed by rules other than Swedish rules, pension benefits and other benefits may be duly adjusted for compliance with mandatory rules or established local practice, taking into account, to the extent possible, the overall purpose of these guidelines.

### ***The guidelines' contribution to the company's business strategy, long-term interests and sustainability***

The business strategy of the company is to provide orthopaedists with individualised, top-quality treatment alternatives via the company's self-developed technology for image analysis, implant design and manufacturing. For more information on the business strategy, please refer to the company's website, [www.episurf.com](http://www.episurf.com). A prerequisite for the successful implementation of the company's business strategy and safeguarding of its long-term interests, including its sustainability, is that the company is able to recruit and retain qualified personnel. The company shall therefore offer remuneration and other terms of employment that enables the company to recruit and retain skilled executives with the experience and competence required. These guidelines enable the company to offer the senior executives a competitive remuneration.

### ***Types of remuneration***

The remuneration shall be on market terms and be competitive, and may consist of the following components: fixed base salary, variable remuneration, pension benefits and other benefits such as company car. Additionally, the general meeting may resolve upon, *inter alia*, share-based remuneration.

### ***Fixed base salary***

Each senior executive shall receive a fixed base salary that enables the company to attract and retain skilled employees. The fixed base salary shall be based on the senior executive's competence, responsibilities and performance.

**Variable remuneration**

The variable remuneration shall be linked to predetermined and measurable criteria which can be financial and non-financial. Financial criteria may relate to turnover, results, share price development and operational efficiency. Non-financial criteria may relate to clinical activities, personnel-related KPIs and quality-related KPIs. The variable remuneration is thereby linked to the company's business strategy, long-term interests and sustainability. The criteria shall be established, assessed and re-evaluated annually. Out of the total variable remuneration, a maximum of 50 percent shall be based on financial criteria and a maximum of 50 percent based on non-financial criteria. The variable remuneration shall not amount to more than 50 percent of the fixed base salary of the senior executive.

**Pension benefits**

The pension benefits of the senior executives shall be defined premium pension benefits, unless the senior executive is subject to defined-benefit pension in accordance with the provisions of a collective agreement. The pension premiums for defined contribution may not exceed 4.5 percent of the annual fixed base salary up to 7.5 Income Base Amounts (Sw. *inkomstbasbelopp*) and 30 percent of the annual fixed base salary exceeding 7.5 Income Base Amounts. Variable remuneration shall only be pensionable to the extent it is required pursuant to applicable provisions of a collective bargaining agreements. Pension benefits may not amount to more than 50 percent of the fixed base salary of the senior executive.

Further, salary exchange shall be possible, allowing senior executives to exchange parts of the monthly fixed salary against pension payments.

**Other benefits**

Remuneration to senior executive may consist of other benefits, for example company car and health insurance. These benefits may not amount to more than 30 percent of the fixed salary of the senior executive.

**Salary and employment conditions for employees**

In the preparation of the board of directors' proposal for these remuneration guidelines, salary and employment conditions for employees of the company have been taken into account by including information on the employees' total income, the components of the remuneration and increase and growth rate over time, in the Board of Directors' basis of decision when evaluating whether the guidelines and the limitations set out herein are reasonable.

**Notice period and severance pay**

The employment agreements between the company and senior executives shall generally apply until further notice. If the company terminates the employment of a senior executive, the notice period may not exceed 12 months. The fixed base salary during the notice period and severance pay may together not exceed an amount corresponding to the fixed base salary for a period of 24 months. When termination is made by the senior executive, the notice period may not exceed six months and may not include any right to severance pay.

**Decision-making process**

The Board of Directors has established a Remuneration Committee. The tasks of the Remuneration Committee includes the preparation of the Board of Directors' proposal for these guidelines. The Board of Directors shall prepare, and submit to the Annual General Meeting, a proposal for new guidelines at least every four years. The guidelines shall apply until new guidelines have been adopted by the Annual General Meeting. The Remuneration Committee shall further monitor and re-evaluate the variable remuneration programs for the senior executives, the application of the guidelines for salary and other remuneration to the senior executives, as well as the current remuneration structures and remuneration levels in Episurf. Senior executives shall not participate insofar as they are affected by the Board of Directors consideration of and decisions on remuneration-related issues.

**Derogation from the guidelines**

The Board of Directors may temporarily resolve to derogate from these guidelines, in whole or in part, if in a specific case there is special cause for such derogation and a derogation is necessary to serve the company's long-term interests, including sustainability, or to ensure the company's financial viability. As indicated above, the tasks of the Remuneration Committee includes the preparation of decisions of the Board of Directors on remuneration-related issues, which includes decisions on deviations from the guidelines.

## Internal control

**AS STATED IN THE SWEDISH COMPANIES ACT AND THE CODE**, the Board of Directors is responsible for ensuring that the company has satisfactory internal controls, for staying informed about the company's internal control system and for assessing the effectiveness of this system. Episurf Medical's internal control work can be divided between the control environment, risk assessment, control activities, information and communication, and monitoring. Episurf Medical's internal audit is handled by the Board of Directors, the CEO and the CFO, but in view of the company's size this is deemed to meet the requirements placed on the company. On a yearly basis, the Board evaluates the need to set up an internal audit function.



### Control environment

Episurf Medical has established a control environment that consists of an organisation with defined decision-making paths, powers and responsibilities. This is governed by policy documents such as the Board's procedural plan, instructions for the CEO, risk management policy, the company's information policy, authorisation procedures and other guidelines and instructions. These are reviewed yearly.

### Risk assessment

The Board of Directors has ultimate responsibility for risk assessment. On a yearly basis, the company evaluates risks and strives to achieve a high level of risk awareness among the employees. The main identified risk areas are financial reporting, operational risks and legal risks.

### Control activities

The Group's business processes include financial controls to avoid errors and mistakes. In order to enter into agreements, pay invoices and similar, an employee must follow defined decision-making paths and authorisation procedures.

### Information and communication

Episurf Medical has been listed since 2010 (at that time on the Aktietorget marketplace) and the company has long experience of external financial communication. The company has an organisation and routines to ensure the correctness and accuracy of the financial reporting. This work is governed by internal control documents that define who is responsible for what in order to ensure that the right information reaches the affected parties in the correct manner.

The company has a comprehensive information policy to safeguard high quality in the external and internal information and ensure that Episurf Medical meets the stock market's requirements for information disclosure. The aim is to convey information in confidence-building manner, externally and internally, so that knowledge and confidence in the company are upheld and enhanced. A separate control document contains routines for press releases, financial reports, general meetings, issues, the website, registration of insiders, handling of the logbook, etc. All reports and press releases are published simultaneously with publication on the company's website.

### Monitoring

The Board of Directors monitors internal control to ensure that shortcomings are corrected and that good ideas are realised, among other things by evaluating the executive management's information.

## Board of Directors

According to the Articles of Association, Episurf Medical's Board of Directors shall consist of at least three and at most eight members, with up to two deputies. The company's Board of Directors currently consists of five members, including the Chairman. All Board members are elected to serve until the end of the next AGM. Below is a presentation of the Board members with information about their year of birth, education, year of election to the Board, other current positions and shareholdings. Assignments in the Group are not stated. Shareholdings in the company include own direct and indirect holdings and related party holdings at 31 December 2020.



**Dennis Stripe**  
**Chairman of the Board since 2016**  
**Shareholding** 304,850 B-shares, 663 TO4B (warrants)  
**Born** 1957

**Education and experience:**

Mr. Dennis Stripe has over 40+ years of experience within the medical device industry. Prior to his involvement in the industry, Mr. Stripe was trained and employed by Goodyear Tire and Rubber, Inc., starting in 1979, as a technical field representative focused on Industrial and Custom products. He was later recruited into the medical device industry in 1983, initiating a medical career where he held various positions within field distribution, product management, and general management on a global basis. Dennis joined a division of Colgate Palmolive Inc., Kendall Healthcare Products, in 1983, and was responsible for major medical device disposable wound care and single-use operating room product brands. His career expanded when Smith and Nephew Plc hired him in 1991 for emerging market development, focused on minimally invasive orthopedic procedures. In 1996, he was hired by Stryker Corporation to establish a US division for Spinal Implant devices, which resulted in major market share increases. In 2008 he began focusing on assisting and directing medical device startup companies, such as CEO of Orthohelix Surgical Designs, Inc. (ultimately acquired by Tornier, Inc, acquired by Wright Medical, now acquired and owned by Stryker Corporation). Mr. Stripe is a 1979 graduate of Ohio Northern University, USA, James F. Dicke School of Business.

**Current positions:** Member of the Board of directors of Medshape Inc., Central Insurance Companies, The Foot and Ankle Association (also known as Step2Walk) and advisor to Compliant Innovations Inc. (Also known as Docspera) and a member of the Board of Trustees of Renew International

**Independence:** Independent in relation to the company, its senior executives and principal shareholders.



**Wilder Fulford**  
**Board member since 2016**  
**Shareholding** 60,000 B-shares  
**Born** 1958

**Education and experience:** Dr Wilder Fulford has advised the Boards, management and owners of companies in diverse industries on M&A, corporate finance and other strategic transactions for over 30 years. Dr Fulford founded The Fulford Group in 2016 to provide independent M&A and strategic and financial advice and execution to companies, entrepreneurs and investors in Life Sciences, Healthcare, and other industries. He also a strategic advisor and member of the investment committee (with the title of Operating Partner) for the Singapore-based private equity firm Quadria Capital, a leading investor in healthcare companies in Asia. In 2011, Dr Fulford founded the London office of Torrey Partners, a specialist life sciences advisory firm. Prior to that he was Head of European Healthcare M&A at Deutsche Bank, Head of European Healthcare Investment Banking at Bank of America, and Head of European Healthcare and Basic Materials M&A at Merrill Lynch. He began his career in New York, working for a number of years as a venture capitalist, and then as an M&A banker at James D. Wolfensohn Inc. and as a partner at Salomon Brothers. In his career he has undertaken hundreds of advisory assignments, and worked on over 100 completed transactions. In recent years, he has advised on numerous healthcare mergers & acquisitions as well as life science and medtech partnering and licensing deals. Dr. Fulford earned a PhD in Molecular Biology from The Rockefeller University in New York and a BSc in Biochemistry from the University of Toronto.

**Current positions:** CEO for the Fulford Group and operating partner at Quadria Capital.

**Independence:** Independent in relation to the company. its senior executives and principal shareholders.



**Leif Ryd**

**Board member since 2009**

**Shareholding** 223 A-shares 308,250 B-shares in person (of which 3,000 is family members), and 421,185 A-shares and 215,714 B-shares through the company Aktiebolaget Gile Medicinkonsult and 2,378 TO4B in person and 15,663 TO4B through the company Aktiebolaget Gile Medicinkonsult (warrants)

**Born** 1949

**Education and experience:** Leif Ryd is an orthopedic surgeon with a long career in clinical research. focusing on osteoarthritis (OA). He is also a former Professor at Karolinska Institute in Stockholm. Dr. Ryd's clinical areas of expertise include degenerative joint disease of the hip and knee, as well as traumatic injuries of the knee. Dr. Ryd works on a consultancy basis for Episurf as a Senior Medical Advisor focusing on medical/scientific development and marketing Episurf products to the medical profession.

**Current positions:** Chairman of the board and CEO of Aktiebolaget Gile Medicinkonsult and member of the Board of directors of Crag AB.

**Independence:** Independent in relation to the company, but not in relation to the company's senior executives and principal shareholders.



**Christian Krüeger**

**Board member since 2016**

**Shareholding** 200,000 B-shares

**Born** 1966

**Education and experience:** Christian Krüeger has a Bachelor of Science in Business Administration and has Majored in Finance at University of Lund. Mr Krüeger is currently the CEO of LMK Venture Partners AB, a Swedish family office investing in both listed, unlisted companies and treasury bond. Mr. Krüeger has extensive experience from the financial industry, including stock and bond brokerage, equity raisings and the debt capital markets. Mr Krüeger has held senior positions, most recently as Head of Equities, at Pareto Securities in Stockholm. Prior to Pareto, Mr Krüeger held multiple senior positions at Öhman Fondkommission and Matteus Fondkommission.

**Current positions:**

Board member of Mälaråsen AB, Solnaberg Property AB, Rocker AB, LMK Venture Partners AB. Deputy director in LMK Ventures AB and Krueger Liljefors Konsult AB.

**Independence:** Independent in relation to the company. its senior executives and principal shareholders.



**Laura Shunk**

**Board member since 2017**

**Shareholding** 200,000 B-shares, 769 TO4B (warrants)

**Born** 1958

**Education and experience:** Laura Shunk is a senior and founding partner in the law firm of Hudak, Shunk and Farine, Co LPA in Cuyahoga Falls, Ohio, USA, where she has practiced in the field of Intellectual Property Law since 1987. Laura's career has included patent and trademark prosecution work focused in the healthcare and medical device field with representations including InvaCare, Cross Medical, Biomet, OrthoHelix Surgical Designs, Tornier, and Wright Medical, among others.

**Current positions:** Chairman of the board of SCI Engineered Materials, Co.

**Independence:** Independent in relation to the company, its senior executives and principal shareholders.

## Executive management



**Pål Ryfors**  
**CEO since 2017**  
**Shareholding** 2,042,757 B-shares  
**Employee stock options** 927,892  
**Warrants** 49,681  
**Born** 1983

**Education and experience:**

Pål has a Bachelor in Financial Economics from Gothenburg School of Economics. He has vast experience from leading positions within the finance and banking sector both in the Nordics

and internationally.

Pål has been CFO of Marginalen Bank, a Swedish bank employing some 350 people. Prior to that, he was Head of Group Controlling at Hoist Finance. Before joining Hoist Finance, he was an investment banker at Societe Generale in London, a position he assumed after holding several leading positions in the restructuring of the Swedish operations of Kaupthing Bank.

**Other appointments:** Board member Aros Kapital AB, Aros Kapital Ltd and Doxa AB



**Veronica Wallin**  
**CFO since 2017**  
**Shareholding** 36,500 B-Shares  
**Employee stock options** 540,632  
**Warrants** 34,748  
**Born** 1986

**Education and experience:** Veronica Wallin has a Degree of Master of Science in Business and Economics from Stockholm's University and was employed by Episurf Medical in August 2016 as Head of Finance. In June 2017 Veronica became CFO after Pål Ryfors, who then assumed the position as CEO. Prior to joining Episurf Medical Veronica worked as Head of

Finance at ApoEx during 2013–2016.

**Other appointments:** -



**Katarina Flodström**  
**COO since 2019**  
**Shareholding** 103,125 B-Shares (of which 28,875 is family members)  
**Employee stock options** 547,848  
**Warrants** 21,755 (of which 259 is family members)  
**Born** 1975

**Education and experience:** Katarina has a PhD in Physical Chemistry from Lund University and a MSc in Chemical Engineering from the Royal Institute of Technology in Stockholm. She was employed by Episurf Medical in 2014. Katarina has over 15 years' experience from RnD in start-up companies. She was the RnD Manager and Quality Manager of Diamorph AB from

which Episurf is a spin-off.

**Other appointments:** Board member Bostadsrättsföreningen Oscar.



**Fredrik Zetterberg**  
**Marketing Director since 2017**  
**Shareholding** 26,500 B-Shares  
**Employee stock options** 551,652  
**Warrants** 22,700  
**Born** 1975

**Education and experience:** Fredrik Zetterberg was employed by Episurf Medical AB in February 2016 and has 20 years of experience from medical technology companies such as Baxter, Cardinal Health, ArthroCare and Smith & Nephew. Since 2008 the focus has been on orthopedics where he has held senior positions within sales management and international

marketing.

**Other appointments:** –



**Michael Näsström**  
**Head of Quality & Regulatory affairs since 2021**  
**Shareholding** 4,000 B-Shares  
**Employee stock options** 206,814  
**Warrants** 10,000  
**Born** 1989

**Education and experience:**

Michael has a Master of Science in Medical Engineering from the Royal Institute of Technology in Stockholm and was employed by Episurf Medical in October 2018.

Previously Michael has been working as a consultant within the life science and medical device industry, of which one year was spent at Episurf Medical.

**Other appointments:** –

## Financial statements, contents

|                                                                      |    |
|----------------------------------------------------------------------|----|
| Consolidated income statement .....                                  | 56 |
| Consolidated statement of comprehensive income .....                 | 56 |
| Consolidated balance sheet .....                                     | 57 |
| Consolidated statement of changes in equity .....                    | 58 |
| Consolidated cash flow statement .....                               | 59 |
| Parent Company income statement .....                                | 60 |
| Parent Company statement of comprehensive income .....               | 60 |
| Parent Company balance sheet .....                                   | 61 |
| Parent Company statement of changes in equity .....                  | 62 |
| Parent Company cash flow statement .....                             | 63 |
| Accounting policies and notes .....                                  | 64 |
| Note 1 General information .....                                     | 64 |
| Note 2 Summary of key accounting principles .....                    | 64 |
| Note 3 Financial risk management .....                               | 70 |
| Note 4 Key accounting estimates and judgements .....                 | 71 |
| Note 5 Segment information .....                                     | 72 |
| Note 6 Operating income .....                                        | 72 |
| Note 7 Financial income and expenses .....                           | 73 |
| Note 8 Other external expenses .....                                 | 73 |
| Note 9 Employees and personnel costs .....                           | 73 |
| Note 10 Income tax .....                                             | 77 |
| Note 11 Intangible assets .....                                      | 78 |
| Note 12 Property, plant and equipment .....                          | 78 |
| Note 13 Shares in group companies .....                              | 79 |
| Note 14 Related party transactions .....                             | 79 |
| Note 15 Trade receivables .....                                      | 79 |
| Note 16 Inventories .....                                            | 80 |
| Note 17 Prepaid expenses and accrued income .....                    | 80 |
| Note 18 Share capital .....                                          | 80 |
| Note 19 Other liabilities .....                                      | 81 |
| Note 20 Accrued expenses and deferred income .....                   | 81 |
| Note 21 Leases .....                                                 | 81 |
| Note 22 Related party transactions .....                             | 82 |
| Note 23 Significant events after the end of the financial year ..... | 83 |
| Note 24 Pledged assets .....                                         | 84 |

## Consolidated income statement

| mSEK                                                             | Note       | Jan-Dec 2020 | Jan-Dec 2019 |
|------------------------------------------------------------------|------------|--------------|--------------|
| <b>Operating income</b>                                          |            |              |              |
| Net sales                                                        | 5,6        | 5.0          | 4,9          |
| Other operating income                                           | 6          | 2.0          | 0,5          |
| <b>Total income</b>                                              |            | <b>7.0</b>   | <b>5.4</b>   |
| <b>Operation expenses</b>                                        |            |              |              |
| Merchandise                                                      |            | -5.1         | -4.5         |
| Other expenses                                                   | 8          | -33.5        | -39.7        |
| Personnel costs                                                  | 9          | -28.3        | -28.1        |
| Capitalised development expenditure                              |            | 4.1          | 5.5          |
| Depreciation and amortization of equipment and intangible assets | 11, 12, 21 | -7.6         | -7.4         |
| <b>Total operating expenses</b>                                  |            | <b>-70.4</b> | <b>-74.2</b> |
| <b>Operating loss</b>                                            |            | <b>-63.4</b> | <b>-68.9</b> |
| <b>Financial items</b>                                           |            |              |              |
| Financial income, other                                          | 7          | 0.1          | 0.5          |
| Financial expenses, other                                        | 7          | -0.7         | -1.5         |
| <b>Results from net financial items</b>                          |            | <b>-0.5</b>  | <b>-0.9</b>  |
| <b>Loss before tax</b>                                           |            | <b>-63.9</b> | <b>-69.8</b> |
| Tax on income for the year                                       | 10         | 0.0          | 0.0          |
| <b>Loss for the year</b>                                         |            | <b>-63.9</b> | <b>-69.8</b> |
| Earnings per share before and after dilution, SEK                | 9          | -0.39        | -1.04        |

## Consolidated statement of comprehensive income

| mSEK                                                                      | Note | Jan-Dec 2020 | Jan-Dec 2019 |
|---------------------------------------------------------------------------|------|--------------|--------------|
| <b>Net profit</b>                                                         |      | <b>-63.9</b> | <b>-69.8</b> |
| <i>Items that may be reclassified to profit/loss</i>                      |      |              |              |
| Exchange differences arising from the translation of foreign subsidiaries |      | 0.1          | -0.1         |
| <b>Total comprehensive income for the year</b>                            |      | <b>-63.8</b> | <b>-69.9</b> |
| <i>The year's loss and comprehensive income attributable to</i>           |      |              |              |
| Owners of the parent                                                      |      | -63.8        | -69.9        |
| Average number of shares                                                  |      | 162 078 945  | 67 343 023   |

## Consolidated balance sheet

| mSEK                                               | Note | 31 Dec 2020  | 31 Dec 2019 |
|----------------------------------------------------|------|--------------|-------------|
| <b>ASSETS</b>                                      |      |              |             |
| <b>Non-current assets</b>                          |      |              |             |
| <i>Intangible fixed assets</i>                     |      |              |             |
| Capitalised development costs                      | 11   | 6.7          | 8.0         |
| Patents                                            | 11   | 14.1         | 13.5        |
| <b>Total intangible fixed assets</b>               |      | <b>20.8</b>  | <b>21.5</b> |
| <i>Equipment and right-of use asset</i>            |      |              |             |
| Rights-of-use asset                                | 21   | 3.8          | 5.9         |
| Equipment                                          | 12   | 0.0          | 0.1         |
| <b>Total equipment and right-of use asset</b>      |      | <b>3.8</b>   | <b>6.0</b>  |
| <i>Non-current financial assets</i>                |      |              |             |
| Other non-current financial assets                 |      | 0.5          | -           |
| <b>Total non-current financial assets</b>          |      | <b>0.5</b>   | <b>-</b>    |
| <b>Total non-current assets</b>                    |      | <b>25.1</b>  | <b>27.5</b> |
| <b>Current assets</b>                              |      |              |             |
| Inventories                                        | 16   | 2.0          | 1.8         |
| Trade receivables                                  | 15   | 0.6          | 0.7         |
| Other receivables                                  |      | 0.9          | 1.3         |
| Prepaid expenses and accrued income                | 17   | 1.9          | 1.1         |
| Cash                                               |      | 155.0        | 25.3        |
| <b>Total current assets</b>                        |      | <b>160.3</b> | <b>30.2</b> |
| <b>TOTAL ASSETS</b>                                |      | <b>185.4</b> | <b>57.6</b> |
| <b>EQUITY AND LIABILITIES</b>                      |      |              |             |
| <b>Equity attributable to owners of the parent</b> |      |              |             |
| Share capital                                      | 18   | 66.7         | 27.3        |
| Other contributed capital                          | 18   | 546.2        | 394.6       |
| Reserves                                           | 18   | -0.2         | -0.4        |
| Accumulated deficit incl. Loss for the year        | 18   | -443.2       | -380.1      |
| <b>Total equity</b>                                |      | <b>169.5</b> | <b>41.4</b> |
| <b>Liabilities</b>                                 |      |              |             |
| <i>Non-current liabilities</i>                     |      |              |             |
| Non-current liabilities                            |      | 0.6          | 0.0         |
| Non-current lease liability                        | 21   | 1.5          | 3.5         |
| <b>Total long-term liabilities</b>                 |      | <b>2.1</b>   | <b>3.5</b>  |
| <i>Current liabilities</i>                         |      |              |             |
| Trade payables                                     |      | 5.4          | 6.0         |
| Current lease liability                            | 21   | 2.4          | 2.4         |
| Other liabilities                                  | 19   | 2.3          | 1.2         |
| Accrued liabilities and deferred income            | 20   | 3.8          | 3.2         |
| <b>Total current liabilities</b>                   |      | <b>13.9</b>  | <b>12.7</b> |
| <b>Total liabilities</b>                           |      | <b>16.0</b>  | <b>16.2</b> |
| <b>TOTAL EQUITY AND LIABILITIES</b>                |      | <b>185.4</b> | <b>57.6</b> |
| Equity ratio                                       |      |              |             |
|                                                    |      | 91.4%        | 71.9%       |
| Equity per share, SEK                              |      |              |             |
|                                                    |      | 0.76         | 0.46        |

## Consolidated statement of changes in equity

| mSEK                                                | Attributable to equity holders of the parent |                           |             |                                             | Total equity |
|-----------------------------------------------------|----------------------------------------------|---------------------------|-------------|---------------------------------------------|--------------|
|                                                     | Share capital                                | Other contributed capital | Reserves    | Accumulated deficit incl. loss for the year |              |
| <b>Opening equity January 1, 2019</b>               | <b>10.5</b>                                  | <b>346.0</b>              | <b>0.5</b>  | <b>-312.1</b>                               | <b>44.8</b>  |
| Reclassification reserves*                          |                                              | -1.1                      | -0.7        | 1.8                                         | -            |
| Total comprehensive income for the period           |                                              |                           |             | -69.8                                       | -69.8        |
| Other comprehensive income                          |                                              |                           | -0.1        |                                             | -0.1         |
| <b>Total comprehensive income</b>                   |                                              |                           | <b>-0.1</b> | <b>-69.8</b>                                | <b>-69.9</b> |
| <b>Transactions with shareholders</b>               |                                              |                           |             |                                             |              |
| Issue in-kind, for conversion of debt**             | 0.7                                          | 2.2                       |             |                                             | 2.9          |
| New share issue, net after issue expenses***        | 16.1                                         | 47.4                      |             |                                             | 63.5         |
| <b>Total transactions with shareholders</b>         | <b>16.8</b>                                  | <b>49.7</b>               |             |                                             | <b>66.3</b>  |
| <b>Closing equity December 31 2019</b>              | <b>27.3</b>                                  | <b>394.6</b>              | <b>-0.4</b> | <b>-380.1</b>                               | <b>41.4</b>  |
| <b>Opening equity January 1, 2020</b>               | <b>27.3</b>                                  | <b>394.6</b>              | <b>-0.4</b> | <b>-380.1</b>                               | <b>41.4</b>  |
| Total comprehensive income for the period           |                                              |                           |             | -63.9                                       | -63.9        |
| Other comprehensive income                          |                                              |                           | 0.1         |                                             | 0.1          |
| Reclassification reserves*                          |                                              |                           | 0.0         | -0.0                                        | 0.0          |
| <b>Total comprehensive income</b>                   |                                              |                           | <b>0.1</b>  | <b>-63.9</b>                                | <b>-63.8</b> |
| <b>Transactions with shareholders</b>               |                                              |                           |             |                                             |              |
| New share issue, net after issue expenses****       | 28.3                                         | 100.5                     |             |                                             | 128.8        |
| Directed share issue, net after issue expenses***** | 11.1                                         | 50.9                      |             |                                             | 61.9         |
| Conversion warrants, net after issue expenses*****  | 0.1                                          | 0.2                       |             |                                             | 0.2          |
| Warrants issued to staff                            |                                              | 0.1                       |             | 0.8                                         | 0.9          |
| <b>Total transactions with shareholders</b>         | <b>39.4</b>                                  | <b>151.6</b>              |             | <b>0.8</b>                                  | <b>191.8</b> |
| <b>Closing equity December 31, 2020</b>             | <b>66.7</b>                                  | <b>546.2</b>              | <b>-0.2</b> | <b>-443.2</b>                               | <b>169.5</b> |

\* Correction of previous classification.

\*\* See more information about the financing agreement under the administration report.

\*\*\* Issue expenses amount to SEK 11.6m.

\*\*\*\* Issue expenses amounts to SEK 12.4m.

\*\*\*\*\* Issue expenses amounts to SEK 4.3m.

\*\*\*\*\* Expenses amounts to SEK 0.0m.

## Consolidated cash flow statement

| mSEK                                                                      | Note       | Jan-Dec 2020 | Jan-Dec 2019 |
|---------------------------------------------------------------------------|------------|--------------|--------------|
| <b>Operating activities</b>                                               |            |              |              |
| Operating loss                                                            |            | -63.4        | -68.9        |
| <i>Adjustments for items not included in cash flow</i>                    |            |              |              |
| Depreciation                                                              | 11, 12, 21 | 7.6          | 7.4          |
| Employee stock option expenses                                            |            | 1.4          | 0.1          |
| Interest received                                                         |            | 0.0          | 0.0          |
| Interest paid                                                             |            | -0.0         | -0.3         |
| <b>Cash flow from current operations before change in working capital</b> |            | <b>-54.3</b> | <b>-61.7</b> |
| <b>Change in working capital</b>                                          |            |              |              |
| Decrease/increase in inventory                                            |            | -0.2         | -0.3         |
| Decrease/increase in trade receivables                                    |            | 0.2          | 0.1          |
| Decrease/increase in current receivables                                  |            | -0.8         | -0.5         |
| Decrease/increase in current liabilities                                  |            | 1.0          | 3.3          |
| <b>Change in working capital</b>                                          |            | <b>0.2</b>   | <b>2.6</b>   |
| <b>Cash flow from operating activities</b>                                |            | <b>-54.1</b> | <b>-59.2</b> |
| <b>Investing activities</b>                                               |            |              |              |
| Investments of intangible fixed assets                                    |            | -4.6         | -5.5         |
| Total non-current financial assets                                        |            | -0.5         | -            |
| <b>Cash flow from investing activities</b>                                |            | <b>-5.1</b>  | <b>-5.5</b>  |
| <b>Financing activities</b>                                               |            |              |              |
| Issuance of share options                                                 |            | 0.1          | -            |
| Amortisation of lease debt                                                | 21         | -2.2         | -2.0         |
| New share issue                                                           |            | 190.9        | 63.6         |
| <b>Cash flow from financing activities</b>                                |            | <b>188.8</b> | <b>61.6</b>  |
| <b>Cash flow for the year</b>                                             |            | <b>129.7</b> | <b>-3.0</b>  |
| Cash and cash equivalents at beginning of year                            |            | 25.3         | 28.3         |
| <b>Cash and cash equivalents at end of year</b>                           |            | <b>155.0</b> | <b>25.3</b>  |

## Parent Company income statement

| mSEK                                                                                | Note   | Jan-Dec 2020 | Jan-Dec 2019 |
|-------------------------------------------------------------------------------------|--------|--------------|--------------|
| <b>Operating income</b>                                                             |        |              |              |
| Net sales                                                                           | 6      | 0.5          | 0.6          |
| Other operating income                                                              |        | 1.5          | 0.0          |
| <b>Total income</b>                                                                 |        | <b>2.0</b>   | <b>0.6</b>   |
| <b>Operating costs</b>                                                              |        |              |              |
| Other external expenses                                                             | 8      | -23.8        | -26.5        |
| Personnel costs                                                                     | 9      | -13.7        | -12.6        |
| Capitalised development expenditure                                                 |        | 1.1          | 1.1          |
| Amortisation of intangible assets and depreciation of property, plant and equipment | 11, 12 | -2.5         | -2.6         |
| <b>Total operating costs</b>                                                        |        | <b>-38.9</b> | <b>-40.6</b> |
| <b>Operating loss</b>                                                               |        | <b>-36.9</b> | <b>-40.0</b> |
| <b>Financial items</b>                                                              |        |              |              |
| Financial income, other                                                             | 7      | 0.0          | 0.0          |
| Financial expenses, other                                                           | 7      | -0.0         | -0.9         |
| <b>Results from net financial items</b>                                             |        | <b>0.0</b>   | <b>-0.9</b>  |
| <b>Loss before tax</b>                                                              |        | <b>-36.8</b> | <b>-40.9</b> |
| Tax on income for the year                                                          | 10     | -            | -            |
| <b>Loss at end of the year</b>                                                      |        | <b>-36.8</b> | <b>-40.9</b> |

## Parent Company statement of comprehensive income

| mSEK                                                | Note | Jan-Dec 2020 | Jan-Dec 2019 |
|-----------------------------------------------------|------|--------------|--------------|
| <b>Net profit</b>                                   |      | <b>-36.8</b> | <b>-40.9</b> |
| <i>Other comprehensive income for the year:</i>     |      |              |              |
| Other comprehensive income for the year, net of tax |      | -            | -            |
| <b>Total comprehensive income for the year</b>      |      | <b>-36.8</b> | <b>-40.9</b> |

## Parent Company balance sheet

| mSEK                                       | Note | 31 Dec 2020  | 31 Dec 2019  |
|--------------------------------------------|------|--------------|--------------|
| <b>ASSETS</b>                              |      |              |              |
| <b>Fixed assets</b>                        |      |              |              |
| <i>Intangible fixed assets</i>             |      |              |              |
| Capitalised development costs              | 11   | 6.7          | 8.0          |
| <b>Total intangible fixed assets</b>       |      | <b>6.7</b>   | <b>8.0</b>   |
| <i>Tangible fixed assets</i>               |      |              |              |
| Equipment                                  | 12   | 0.0          | 0.0          |
| <b>Total tangible fixed assets</b>         |      | <b>0.0</b>   | <b>0.0</b>   |
| <b>Financial assets</b>                    |      |              |              |
| Shares in group companies                  | 13   | 162.9        | 137.4        |
| Long-term receivables from group companies | 14   | 33.2         | 20.0         |
| Other non-current financial receivables    | 14   | 0.5          | -            |
| <b>Total financial assets</b>              |      | <b>196.6</b> | <b>157.4</b> |
| <b>Total fixed assets</b>                  |      | <b>203.2</b> | <b>165.4</b> |
| <b>Current assets</b>                      |      |              |              |
| <i>Short term receivables</i>              |      |              |              |
| Other receivables                          |      | 0.6          | 0.8          |
| Prepaid expenses and accrued income        | 17   | 1.7          | 0.9          |
| <b>Total short term receivables</b>        |      | <b>2.3</b>   | <b>1.6</b>   |
| Cash                                       |      | 134.8        | 18.1         |
| <b>Total current assets</b>                |      | <b>137.1</b> | <b>19.8</b>  |
| <b>TOTAL ASSETS</b>                        |      | <b>340.3</b> | <b>185.2</b> |
| <b>EQUITY AND LIABILITIES</b>              |      |              |              |
| <b>Equity</b>                              |      |              |              |
|                                            | 18   |              |              |
| Restricted equity                          |      |              |              |
| Share capital                              |      | 66.7         | 27.3         |
| Development fund                           |      | 6.7          | 7.4          |
| <b>Total restricted equity</b>             |      | <b>73.3</b>  | <b>34.7</b>  |
| <b>Unrestricted equity</b>                 |      |              |              |
| Share premium reserve                      |      | 546.2        | 394.6        |
| Loss brought forward                       |      | -250.4       | -210.2       |
| Loss for the year                          |      | -36.8        | -40.9        |
| <b>Total unrestricted equity</b>           |      | <b>259.1</b> | <b>143.5</b> |
| <b>Total equity</b>                        |      | <b>332.4</b> | <b>178.2</b> |
| <b>Liabilities</b>                         |      |              |              |
| <b>Current liabilities</b>                 |      |              |              |
| Trade payables                             |      | 3.5          | 4.3          |
| Other liabilities                          | 19   | 1.4          | 0.4          |
| Accrued liabilities and deferred income    | 20   | 3.1          | 2.3          |
| <b>Total current liabilities</b>           |      | <b>7.9</b>   | <b>7.0</b>   |
| <b>Total liabilities</b>                   |      | <b>7.9</b>   | <b>7.0</b>   |
| <b>TOTAL EQUITY AND LIABILITIES</b>        |      | <b>340.3</b> | <b>185.2</b> |

## Parent Company statement of changes in equity

| mSEK                                               | Share capital | Development fund | Share premium reserve | Loss brought forward | Loss for the period | Total equity |
|----------------------------------------------------|---------------|------------------|-----------------------|----------------------|---------------------|--------------|
| <b>Opening equity January 1, 2019</b>              | <b>10.5</b>   | <b>7.9</b>       | <b>344.9</b>          | <b>-181.0</b>        | <b>-29.7</b>        | <b>152.6</b> |
| Comprehensive loss for the year*****               |               |                  |                       |                      | -40.9               | -40.9        |
| Disposition according to AGM                       |               |                  |                       |                      |                     |              |
| Loss brought forward                               |               |                  |                       | -29.7                | 29.7                | -            |
| Deposition/resolution development fund*            |               | -0.4             |                       | 0.4                  |                     | -            |
| <b>Total comprehensive loss for the period</b>     |               | <b>-0.4</b>      |                       | <b>-29.2</b>         | <b>-11.2</b>        | <b>-40.9</b> |
| <b>Transactions with shareholders</b>              |               |                  |                       |                      |                     |              |
| Issue in-kind, for conversion of debt*             | 0.7           |                  | 2.2                   |                      |                     | 2.9          |
| New share issue, net after issue expenses**        | 16.1          |                  | 47.4                  |                      |                     | 63.6         |
| <b>Total transactions with shareholders</b>        | <b>16.8</b>   |                  | <b>49.7</b>           |                      |                     | <b>66.5</b>  |
| <b>Closing equity December 31, 2019</b>            | <b>27.3</b>   | <b>7.4</b>       | <b>394.6</b>          | <b>-210.2</b>        | <b>-40.9</b>        | <b>178.2</b> |
| <b>Opening equity January 1, 2020</b>              | <b>27.3</b>   | <b>7.4</b>       | <b>394.6</b>          | <b>-210.2</b>        | <b>-40.9</b>        | <b>178.2</b> |
| Comprehensive loss for the year*****               |               |                  |                       |                      | -36.8               | -36.8        |
| Disposition according to AGM                       |               |                  |                       |                      |                     |              |
| Loss brought forward                               |               |                  |                       | -40.9                | 40.9                | -            |
| Deposition/resolution development fund*            |               | -0.8             |                       | 0.8                  |                     | -            |
| <b>Total comprehensive loss for the period</b>     |               | <b>-0.8</b>      |                       | <b>-40.1</b>         | <b>4.1</b>          | <b>-36.8</b> |
| <b>Transactions with shareholders</b>              |               |                  |                       |                      |                     |              |
| New share issue, net after issue expenses***       | 28.3          |                  | 100.5                 |                      |                     | 128.8        |
| Directed share issue, net after issue expenses**** | 11.1          |                  | 50.9                  |                      |                     | 61.9         |
| Conversion warrants, net after issue expenses***** | 0.1           |                  | 0.2                   |                      |                     | 0.2          |
| Warrants issued to staff                           |               |                  | 0.1                   |                      |                     | 0.1          |
| <b>Total transactions with shareholders</b>        | <b>39.4</b>   |                  | <b>151.6</b>          |                      |                     | <b>191.0</b> |
| <b>Closing equity December 31, 2020</b>            | <b>66.7</b>   | <b>6.7</b>       | <b>546.2</b>          | <b>-250.4</b>        | <b>-36.8</b>        | <b>332.4</b> |

\*See more information about the financing agreement under the administration report.

\*\* Issue expenses amounts to SEK 11.6m.

\*\*\* Issue expenses amount to SEK 12.4m.

\*\*\*\* Issue expenses amounts to SEK 4.3m.

\*\*\*\*\* Expenses amounts to SEK 0.0m.

\*\*\*\*\* Comprehensive loss for the year coincides with the total loss for the year.

\*\*\*\*\* The change for the year refers to the net of capitalised internally developed intangible assets and amortisation of these assets.

## Parent Company cash flow statement

| mSEK                                                                       | Note   | Jan-Dec 2020 | Jan-Dec 2019 |
|----------------------------------------------------------------------------|--------|--------------|--------------|
| <b>Current operations</b>                                                  |        |              |              |
| Operating loss                                                             |        | -36.9        | -40.0        |
| <i>Adjustments for items not included in cash flow</i>                     |        |              |              |
| Depreciation                                                               | 11, 12 | 2.5          | 2.6          |
| Interest received                                                          |        | 0.0          | 0.0          |
| Interest paid                                                              |        | -0.0         | -0.0         |
| <b>Cash flow from current activities before changes in working capital</b> |        | <b>-34.4</b> | <b>-37.4</b> |
| <b>Changes in working capital</b>                                          |        |              |              |
| Decrease/increase in current receivables                                   |        | -0.7         | -0.4         |
| Decrease/increase in current liabilities                                   |        | 1.0          | 2.7          |
| <b>Total changes in working capital</b>                                    |        | <b>0.3</b>   | <b>2.3</b>   |
| <b>Cash flow from operating activities</b>                                 |        | <b>-34.1</b> | <b>-35.2</b> |
| <b>Cash flow from investing activities</b>                                 |        |              |              |
| Acquisition subsidiary                                                     |        | -            | -0.1         |
| Acquisition of intangible assets                                           |        | -1.1         | -1.1         |
| Shareholder contribution                                                   | 13     | -25.5        | -30.5        |
| Repaid group companies                                                     | 14     | 36.1         | 33.9         |
| Loan group companies                                                       | 14     | -49.2        | -30.0        |
| Decrease/increase in other non-current receivables                         |        | -0.5         | -            |
| <b>Cash flow from investing activities</b>                                 |        | <b>-40.3</b> | <b>-27.9</b> |
| <b>Cash flow from financing activities</b>                                 |        |              |              |
| Issuance of share options                                                  |        | 0.1          | -            |
| New share issue                                                            |        | 190.9        | 63.6         |
| <b>Cash flow from financing activities</b>                                 |        | <b>191.0</b> | <b>63.6</b>  |
| <b>Cash flow for the year</b>                                              |        | <b>116.6</b> | <b>0.6</b>   |
| Cash and cash equivalents at beginning of year                             |        | 18.1         | 17.6         |
| <b>Cash and cash equivalents at end of year</b>                            |        | <b>134.8</b> | <b>18.1</b>  |

## Accounting policies and notes

### Note 1 General information

Episurf Medical AB (publ) is a Swedish medical device group that endeavours to help people with joint pain live a more active life by providing them with effective and personalised treatments. The patient-specific technology has been developed in collaboration with leading universities and clinical centers in Sweden. The Parent Company is a limited liability company that is registered in Sweden and is domiciled in Stockholm. The visiting address of the head office is Karlavägen 60, Stockholm, Sweden.

The consolidated financial statements and annual report were approved by the Board of Directors for publication on March 30, 2020. All amounts are presented in mSEK unless otherwise stated. Information in parentheses refers to the previous year.

### Note 2 Summary of key accounting principles

The consolidated financial statements of the Episurf Medical AB (publ) AB Group are presented in compliance with the International Financial Reporting Standards (IFRS) as endorsed for application in the EU. RFR 1. Supplementary Accounting Rules for Groups.

The consolidated financial statements have been prepared on the historical cost basis.

The most important accounting policies applied in the preparation of these consolidated financial statements are described below. These policies have been consistently applied in all years presented, unless otherwise stated. The financial statements of the Parent Company are presented in compliance with RFR 2. Accounting for Legal Entities, and the Swedish Annual Accounts Act. The cases where the accounting policies applied by the Parent Company differ from those of the Group are described separately at the end of this note. The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the company's accounting policies. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements, are described in Note 4, Critical accounting estimates and judgements.

#### Changed accounting principles

The changed standards that came into force in 2020 have not had any significant effect on the Group.

#### Subsidiaries

Subsidiaries are all companies in which the Group has control over the investment, is exposed to or is entitled to variable returns from its involvement in the investment and can use its control over the investment object to influence the size of its return. Subsidiaries are consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date that control ceases.

Business combinations are accounted for using the acquisition method. The purchase consideration for the acquisition of a subsidiary consists of the acquisition-date fair value of assets acquired, equity instruments issued and liabilities assumed, plus costs that are directly attributable to the acquisition. The identifiable assets acquired and liabilities assumed in a business combination are initially measured at the acquisition-date fair value, regardless of the amount of any non-controlling interests. Goodwill is initially measured at cost and represents the difference between the fair value of purchase consideration given in connection with an acquisition and the Group's share in the fair value of identifiable net assets acquired and liabilities and contingent liabilities assumed. If the fair value of consideration transferred is lower than fair value of the acquired subsidiary's assets, liabilities and contingent liabilities, the difference is recognised immediately in profit or loss.

All intra-group transactions and balances and unrealised gains relating to transactions between group companies are eliminated. Unrealised losses are also eliminated but are regarded as an indication of impairment. When necessary, the accounting policies of subsidiaries have been adjusted to ensure conformity with the accounting policies of the Group.

At present, the Group has no subsidiaries with non-controlling interests. The Swedish subsidiaries in the Group were formed in 2013, the Germany and English subsidiaries were formed in 2015 and in 2018, the US and Indian companies were formed.

## **Foreign currencies**

### ***Functional and presentation currency***

Items included in the financial information of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the functional currency). The presentation currency of the Group is Swedish kronor (SEK), which is also the functional currency of the Parent Company and the Swedish subsidiaries. Other subsidiaries functional currency is their national currency.

### ***Transactions in foreign currency***

Transactions in foreign currency are translated to the functional currency at the rate of exchange ruling on the dates of the transactions. Foreign exchange gains/losses arising on the payment of such transactions and in translation of monetary assets and liabilities in foreign currency at the closing day rate are recognised in profit or loss. Exchange differences on borrowings and loans are recognised in net financial items, which other exchange differences are recognised in operating profit. At present, the Group has no borrowings or loans in foreign currency, only operating receivables and liabilities.

## **Intangible assets**

### ***Patents***

Patents are stated at cost. Patents have a definite useful life and are recognised at cost less accumulated amortisation.

These are amortised on a straight-line basis to allocate the cost of the patent over its estimated useful life (5 years).

### ***Capitalised development expenditures***

Development expenditure that is directly attributable to development and testing of identifiable and unique products that are controlled by the Group is recognised in intangible assets when it meets the following criteria:

- » It is technically feasible to complete the product so it can be used or sold,
- » The company intends to complete the product and use or sell it,
- » The company is able to use or sell the product,
- » The company can show how the product will generate future economic benefits,
- » The company has adequate technical, financial and other resources to complete development and to use or sell the product, and
- » The cost of completing development of the product can be measured reliably.

The directly attributable costs that are capitalised as part of the capitalised development expenditure include costs for employees and a reasonable share of indirect costs.

Other development expenses that do not meet the above criteria are expensed as incurred. Development expenses that have been previously expensed are not recorded as assets in subsequent periods.

The company amortises capitalised development expenditure relating to the development projects or finished products that have started to generate revenue. These are amortised on a straight-line basis to allocate the cost of the patent over its estimated useful life (5 years).

Capitalised development expenditure is tested for impairment at least yearly by the company.

## **Property, plant and equipment**

Items of property, plant and equipment are stated at cost less accumulated depreciation and impairment losses. The historical cost includes costs that can be directly attributed to the acquisition.

Subsequent expenditure is added to the carrying amount of the asset or recorded as a separate asset, according to what is appropriate, only when it is probable that the future economic benefits associated with the asset will flow to the Group and the cost of the asset can be estimated reliably. The carrying amount for the replaced portion is derecognised from the balance sheet. All other types of repairs and maintenance are accounted for as costs in the income statement in the period in which they arise.

To allocate the depreciable amount (cost less residual value) over the estimated useful life, other assets are depreciated on a straight-line basis as follows:

### **Equipment**

The carrying amounts of the Group's assets are reviewed at each balance sheet date to look for any indication that an asset may be impaired. An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Gains and losses on disposals are determined by comparing the proceeds with the carrying amount and are recognised in other operating income and other operating expenses in the income statement.

**Impairment of non-financial assets**

Property, plant and equipment and amortisable intangible assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised in the amount whereby the asset's carrying amount exceeds its recoverable amount. Recoverable amount is the higher of the asset's value in use and its fair value less costs to sell.

For the purpose of testing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units). Property, plant and equipment and intangible assets for which an impairment loss has been previously recognised are tested at each balance sheet date to determine whether the impairment loss should be reversed.

The recoverable amount is the higher of the fair value, less selling costs, and value in use. When calculating the value in use, future cash flows are discounted with a discounting factor that takes into account risk-free interest rates and the risk associated with the specific risk.

**Inventories**

Inventories are stated at the lower of cost and net realisable value. Cost is determined using the first-in, first-out method (FIFO). The historical cost of goods for resale consists of the cost of purchasing the goods. Borrowing costs are not included. Net realisable value is calculated as the estimated selling price in the ordinary course of business less directly attributable variable selling expenses. The requisite provisions for obsolescence are made after individual assessment.

**Financial instruments**

The Group classifies financial assets and liabilities in accordance with IFRS 9. The classification determines how the financial instruments are valued and recognized based on their classification. The Group's principles for classifying and valuing financial assets are based on an assessment of both (i) the company's business model for the management of financial assets, and (ii) the characteristics of the contractual cash flows from the financial asset.

Financial assets valued at amortised cost are debt instruments that are managed with the aim of realising the cash flow of the instruments by obtaining contractual cash flows that consist solely of capital amounts and interest on the outstanding capital amount. The following financial assets are valued at amortised cost because the assets are held within the framework of a business model whose objective is to keep financial assets with the purpose of collecting contractual cash flows and that the agreed terms for those assets give rise to cash flows which are only payments at specified times of principal and interest on the outstanding amount of capital;

- Other non-current financial receivables
- Accounts receivables
- Other receivables
- Accrued income
- Cash and cash equivalents

All of the Group's financial liabilities, consisting of borrowing, accounts payable and accrued expenses, are recognised at amortised cost.

Financial instruments are initially recognized at fair value with additions/deductions for transaction expenses, except for instruments that are continuously measured at fair value through profit or loss for which transaction expenses are instead expensed when they arise. Accounts receivable (without a significant financing component) are initially valued at the transaction price determined in accordance with IFRS15 Revenue from agreements with customers. The normal credit period with suppliers is 30 days.

**Accounts and other receivables**

Accounts receivable and other receivables are initially recognised at fair value and subsequently at amortised cost using the effective interest method, less any provision for impairment.

**Recognition and derecognition in the balance sheet**

A financial asset or financial liability is recognised in the balance sheet when the Group becomes a party under the instrument's contractual terms with the exception of accounts receivable that are recognized when they are issued.

The Group removes a financial asset from the statement of financial position when the contractual rights to the cash flows from the financial asset cease or if it transfers the right to receive the contractual cash flows through a transaction in which substantially all risk and rewards of ownership have been transferred or in which the Group does not mainly transfer or retain all the risks and rewards of ownership, and it does not maintain control over the financial asset.

The Group removes a financial liability from the statement of financial position when the commitments specified in the agreement are fulfilled, canceled, or terminated. The Group also removes a financial liability from the

statement of financial position when the commitments specified in the agreement are fulfilled, canceled, or terminated. The Group also removes a financial liability when the contractual terms are modified, and the cash flows from the adjusted debt are significantly different. In this case, a new financial liability is recognised at fair value based on the modified terms.

A financial asset and a financial liability are offset and reported with a net amount in the balance sheet only when there is a legal right to offset the amounts and that there is an intention to settle the items with a net amount or to simultaneously realise the asset and regulate the debt.

#### ***Impairment of financial assets***

The reserve for expected credit losses is calculated and reported for the financial assets that are valued at amortised cost. The reserve for loan losses is calculated and reported initially on the basis of twelve-month expected loan losses. If the credit risk has increased significantly since the financial asset was first recognised, the reserve for credit losses is calculated and reported based on expected loan losses for the entire remaining term of the asset. For accounts receivable, which do not contain a significant financing component, a simplified method is applied, and the reserve for credit losses is calculated and reported on the basis of expected loan losses for the entire remaining term, regardless of whether the credit risk has increased significantly or not. The calculation of expected loan losses is mainly based on information on historical losses for similar receivables and counterparties. The historical information is evaluated and adjusted continuously based on the current situation and the Group's expectation of future events.

#### **Cash**

Cash include bank balances.

#### **Share capital**

Common shares are classified as equity. Transaction costs that can be directly attributed to the issue of new shares are recognised, net of tax, in equity among other contributed capital on a separate line as a deduction from the issue proceeds.

#### **Issued convertible bonds**

Convertible debentures that can be converted into shares by the counterparty exercising its option to convert the right to a claim into shares are reported as a composite financial instrument divided into a liability component and an equity component. The fair value of the debt at the time of issue is calculated by discounting the future payment flows with the current market interest rate for similar debt, without the right to conversion. The value of the equity instrument is calculated as the difference between the issue proceeds when the convertible debenture was issued and the fair value of the financial liability at the time of issue. Any deferred tax attributable to the liability at the time of issue is deducted from the carrying amount of the equity instrument. Transaction costs in connection with the issuance of a compound financial instrument are allocated to the liability component and the equity component proportionally to how the issue proceeds are distributed. Interest expense is recognised in profit for the year and is calculated using the effective interest method.

#### **Current and deferred tax**

The current income tax expense is calculated on the basis of the tax laws that have been enacted or substantively enacted at the balance sheet date in the countries where the Parent Company and its subsidiaries operate and generate taxable income. Management regularly evaluates the claims made in income tax returns regarding situations where the applicable tax rules are subject to interpretation and, when deemed appropriate, makes provisions for amounts that are likely to be paid to the tax authorities. Deferred tax is recognised in full, in accordance with the balance sheet method, on all temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. However, deferred tax is not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantively enacted by the balance sheet date and are expected to apply when the related deferred income tax asset is realised or the deferred tax liability is settled. Deferred tax assets are recognised only to the extent that it is probable that future taxable profit will be available against which they can be used.

#### **Employee benefits**

The cost of providing employee benefits in the form of salary and pension is recognised in the period in which the benefit is earned by the employee.

#### **Pension obligations**

The Group has only defined contribution pension plans. For defined contribution pension plans. Episurf Medical AB (publ) pays contributions to publicly or privately administered pension insurance plans on a mandatory, contractual or voluntary basis. The Group has no further payment obligations when the contributions have been paid. The contributions are

recognised as personnel costs when they fall due for payment. Prepaid contributions are recognised as an asset to the extent that a cash refund or a reduction in the future payments is available to the Group.

#### **Termination benefits**

Termination benefits are payable when employment is terminated by Episurf Medical AB (publ) before the normal retirement date, or whenever an employee accepts voluntary redundancy in exchange for special compensation. Episurf Medical AB (publ) recognises termination benefits when the Group is demonstrably committed to either terminate employment according to a detailed formal plan without realistic possibility of withdrawal, or provide termination benefits as a result of an offer made in order to encourage voluntary redundancy. Benefits falling due more than 12 months after the end of the reporting period are discounted to present value.

#### **Share-based payments**

The fair value of employee stock options granted is recognised as an employee expense with a corresponding increase in equity. The fair value is measured at grant date and spread over the vesting period. The cost reported corresponds to the fair value of an estimate of the number of options that are expected to be earned, taking into account the terms of service that are a prerequisite for earning the options. This cost is adjusted in subsequent periods to finally reflect the actual number of vested options.

Cash-settled options (the cash-bonus) result in a commitment to the employees that is measured at fair value and recognised as an expense with a corresponding increase in liabilities. The fair value is initially measured at grant date and spread over the vesting period. The liability is remeasured at each reporting date and at the date of settlement. All changes in the fair value of the liability are recognised in the profit or loss for the year as a personnel cost.

Social costs relating to employee stock options and the cash-bonus are expensed in the periods in which the services are performed. The charge for social costs is based on the fair value of the stock options and the cash bonus at the time of each report.

#### **Revenue recognition**

##### **Sale of goods**

The Group's revenue is generated by the sale of products. Sales are made to companies. The product range consist of proprietary products.

Revenue is measured at the fair value of the consideration received or receivable for goods sold in the Group's ordinary course of business. Revenue is recognised net less value added tax, returns and discounts.

For agreements that allow customers to return goods, revenue is reported to the extent that is very likely that a substantial reversal of accumulated revenue will not occur. Estimates of expected returns are based on historical data for specific customers and goods. Expected returns are reported as a decrease in revenue and as a debt for repayment, while the associated cost of goods decreases and an asset corresponding to the right to receive returned goods is reported.

Revenue is recognised at the time when the goods have been delivered and, the control over the goods has passed. Customers get control of the goods when the goods are shipped from the Group's warehouse or when the goods have been delivered depending on the contract terms. Invoices are drawn up at this time and usually expire within 30 days.

##### **Sales of licenses**

License revenue refers to the out-licensing of the parent company's patented software platform µiFidelity®. When licensing the Group's intellectual property (IP) to a customer, a distinction is made between two types of licensing with associated distinct performance obligation that affect whether revenue is to be reported at a certain time or accrued over time:

a) Right to access IP - the agreement requires, or the customer can reasonably expect, that the Group will take measures that significantly affect the rights the customer is entitled to, that these measures directly affect the customer and that the measures do not involve the transfer of goods/services to the customer when the measures are carried out. The performance obligation and thus the income is reported over time, usually linearly.

b) Right to use IP - the customer only has the right to use the IP in its existing state at the time when the right was granted to the customer. The performance obligation is fulfilled initially, at that time.

In accordance with the terms of the license agreement, it has been determined to be a right to use IP and recognised at the effective date of the contract.

#### **Government grants**

##### **Government grants research and development projects**

Government grants received for research and development projects are reported net and reduce the personnel costs, over the period necessary to match them with the related costs for which they are intended to compensate.

### **Other government grants**

Received government grants as a result of covid-19 is recognised as personnel costs, as costs arise that the government grants is intended to cover. Episurf Medical had executed short term layoffs in certain parts of the organisation during the financial year. The financial impact has been reported as it is deemed that all conditions have been met. The total amount stated in the income statement is SEK 0.5m during the financial year for the group.

### **Interest income**

Interest income is recognised over the contractual term of the loan using the effective interest rate method.

### **Leases**

When an agreement is entered into, the Group assesses whether the agreement is, or contains a lease agreement. An agreement is, or contains, a lease agreement if the agreement assigns the right to decide over a certain period of use over an identified asset in exchange for compensation. The Group recognizes a right of use and a lease liability at the commencement date of the lease. The right to use the asset is initially valued at cost, which consists of the initial value of the lease debt with the addition of leasing fees paid on or before the commencement date plus any initial direct expenses. The rights of use are depreciated on a straight-line basis from the commencement date until the earlier of the end of the asset's useful life and the end of the lease period, which is normally the end of the leasing period for the Group. The leasing liability - which is divided into long-term and short-term - is initially valued at the present value of remaining leasing fees during the assessed leasing period. The lease period is the non-cancellable period with the addition of additional periods in the agreement if it is deemed reasonably certain that these will be used at the commencement date.

Leasing fees are normally discounted with the Group's marginal borrowing rate, which, in addition to the Group's / Company's credit risk, reflects the respective leasing period, currency, and quality of the underlying asset as intended security.

The lease liability comprises the present value of the following fees during the estimated lease period:

- fixed fees, including fixed fees for its substance,
- variable leasing fees linked to the index or price (initially), valued initially using the index or price ("rate") that applied at the commencement date;

The value of the debt is increased by the interest cost for each period and reduced by the lease payments. Interest expense is calculated as the value of the debt times the discount rate.

The leasing liability for the Group's premises with rent that is indexed is calculated on the rent that applies at the end of each reporting period. At this time, the liability is adjusted with the corresponding adjustment of the reported value of the rights of use. Correspondingly, the value of the debt and the asset is adjusted in connection with the re-evaluation of the lease period. This is done in conjunction with the expiry of the notice period within the previously assessed leasing period for local leases, or when significant events occur, or circumstances change in a significant way in a way that is within the Group's control and affects the current assessment of the leasing period. For leasing contracts that have a leasing period of 12 months or less or with an underlying asset of low value, less than SEK 0.1m, no rights of use and leasing debt are reported. Leasing fees for these leases are recognized as a cost on a straight-line basis over the lease period.

### **Dividends**

Dividends to the Parent Company's shareholders are recognised as a liability in the consolidated financial statements in the period in which the dividends are approved by the Parent Company's shareholders.

### **Accounting policies of the Parent Company**

The Parent Company applies the Swedish Annual Accounts Act and the Swedish Financial Reporting Board's recommendation RFR 2 Accounting for legal entities. The Parent Company applies accounting principles other than the Group in the cases stated below.

### **Financial assets and liabilities**

In the Parent Company, financial fixed assets and current financial assets according to the lowest value principle are valued at cost less any impairment losses. For financial assets that are reported at amortised cost, the impairment rules are applied in IFRS 9

### **Leases**

IFRS 16 Leasing Agreements does not affect the parent company as the standard is exempted from application by a legal entity. As a lessee, leasing fees are recognised as a cost on a straight-line basis over the lease period, and thus rights of use and leasing liabilities are not recognised in the balance sheet.

### **Presentation of the income statement and balance sheet**

The Parent Company uses the presentation stated in the Swedish Annual Accounts Act, which means among other things that a different presentation of equity is applied. In other respects, the income statement and balance sheet are presented in the same manner as in the Group. Certain terminology in the income statement differs between the Group and the Parent Company, which is an effect of the terms used in the Swedish Annual Accounts Act and IFRS.

### **Shares in subsidiaries**

Shares in subsidiaries are recognised at cost less impairment. Dividends received are recognised when the right to receive payment has been established. The shares to which the dividends refer are then tested for impairment. When there is an indication that the value of shares and participations in subsidiaries has decreased, the recoverable amount is calculated. If this is lower than the carrying amount, an impairment loss is recognised. Impairment losses are recognised in profit from shares in group companies.

### **Group and shareholder contributions**

Shareholder contributions paid are recognised as an increase in the investments in subsidiaries. The values of the investments in question are then tested for impairment. A group contribution that the Parent Company receives from a subsidiary is recognised according to the same principles as normal dividends from subsidiaries, which means that the group contribution is recognised in financial income.

### **Fund development expenses**

The amount capitalised for its own accumulated development costs must be brought about from the unrestricted equity to fund development expenditures in restricted equity. The fund will be reduced in line with the capitalised expenses are amortised or down.

### **Rounding**

Due to rounding, the sum of numbers may differ.

## **Note 3 Financial risk management**

### **Financial risk factors**

Through its activities, the Group is exposed to various financial risks: market risk (certain foreign exchange risk and interest rate risk), credit risk and liquidity risk. The Group's overall risk management policy is focused on minimising the potential adverse effects on the Group's financial results.

The identified risks consist mainly of a certain foreign exchange risk resulting from foreign trade.

Risk management is handled by the CEO in consultation with the finance department, based on guidelines established by the Board. The CEO, in consultation with the finance department, identifies, evaluates and hedges financial risks in close cooperation with other senior executives in the Group.

### **Market risk**

#### **a) Foreign exchange risk**

The Group is exposed to foreign exchange risk arising from exposures to different currencies, primarily relating to transactions in the EU and the US. Episurf Medical AB's (publ) presentation currency is Swedish kronor (SEK), which is also the functional currency of the Parent Company and the Swedish subsidiaries in the Group. The financial statements of foreign subsidiaries are presented in local currency and are translated to SEK in the consolidated financial statements. The balance sheets of foreign subsidiaries are translated to SEK at the closing day rate of exchange and all items in the income statement are translated at the average rate during the year. Any translation differences thus arising are recognised in consolidated financial statements in other comprehensive income for the period, net of tax. The company has a currency risk regarding accounts payable and, mainly the increased costs for the company's investment in the US. In 2020 the company incurred costs for the US of SEK 12.3 million, if the dollar exchange rate would go up or down by 5%, it would affect the company by SEK 0.6m.

#### **b) Credit risk**

Credit risk is managed at the group level. Credit risk arises through cash and cash equivalents, deposits in banks and financial institutions and credit exposures to the Group's customers, including outstanding receivables and contractual transactions. The maximum credit exposure consists of the book value of the exposed assets. At present the Group's credit risk is assessed to be limited, since most of the financial assets consist of cash and cash equivalents in major Swedish credit institutions. For cash and cash equivalents consisting of deposit accounts, banks and financial institutions are counterparts, which are graded a3 for the majority of cash and cash equivalents and second largest has ba1 both based on Moody's credit rating.

#### **c) Interest risk**

The Group is exposed to interest rate risk on cash and cash equivalents and interest-bearing short-term liabilities. The Group makes an ongoing assessment of current interest rate risk.

#### **d) Liquidity risk and going concern**

As of December 31, 2020, the group had SEK 155.0m (25.3) in cash and cash equivalents. The group completed a share issue and a directed share issue during the second quarter 2020 and received in total, SEK 141.0m before transaction costs was contributed to the group. During the fourth quarter the group completed a directed share issue and received in total SEK 66m before transaction costs.

Future undiscounted cash flows conforms in all material respects to the book values of the liabilities.

#### **Capital risk management**

The Group's objectives when managing capital are to safeguard the Group's ability to continue as a going concern in order to provide returns for shareholders and benefits for other stakeholders and to maintain an optimal capital structure in order to reduce the cost of capital. The Group is largely financed through equity. The equity ratio at 31 December 2020 was 91.4 percent (71.9).

#### **Fair value**

The Group has no financial assets or liabilities that are measured at fair value. The carrying amount of assets and liabilities in the balance sheet, which falls within the scope of disclosures in accordance with IFRS 13, is assessed to correspond closely to fair value.

### **Note 4 Key accounting estimates and judgements**

Estimates and judgments are evaluated continuously and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

#### **Key accounting estimates and assumptions**

The Group makes estimates and assumptions concerning the future. The resulting accounting estimates will, by definition, rarely correspond to the actual results. The estimates and assumptions that are associated with a significant risk for material adjustments in the carrying amounts of assets and liabilities in the next financial year are described below.

#### **IAS 38 Intangible assets – capitalised development expenditure**

Episurf Medical conducts extensive development activities, which have reached a stage where they have now started to generate revenue for the products, albeit still on a modest scale since the organisation in the Nordic countries and Europe (primarily Germany and the UK) is in the process of being built up.

The company's product development model has several phases and the probability of future economic benefits does not start to crystallise until the later phases. Episurf Medical is working on development of several products and at present there are products that have been abandoned, mothballed or are still at the beginning of the development model. An intangible asset that arises through development, or in the development phase of an internal project, is recognised as an asset in the balance sheet only if the company can demonstrate that all of criteria 1)–6) in Note 2 have been met.

There are two main criteria that are analysed in order to assess historical expenditure and whether it meets the criteria for capitalisation.

1. The probability of future economic benefits, and
2. whether financing had been arranged at the time when the expense was incurred. For 2013 and the preceding period, we assessed that these two criteria had not been fully met. However, since five of the products have now been approved and are starting to be tested in the market, at the beginning of the fourth quarter of 2014 the company decided to start capitalising development expenses.

### Valuation of loss carry forwards

Every year, the Group examines whether there is any indication of impairment of deferred tax assets relating to tax loss carry forwards. Furthermore, the Group examines the opportunities to capitalise new deferred tax assets with respect to the year's tax loss carry forwards, if appropriate. The deferred tax asset is recognised only when it is probable that there will be future taxable profits against which the temporary difference can be utilised. The carrying amounts of the deferred tax asset on the respective balance sheet dates are shown in Note 10. At 31 December 2020 the Group had loss carry forwards amounting to SEK 443.5m (377.3) that had not been included in calculation of the deferred tax asset.

### Going concern

As of December 31, 2020, the group had SEK 155.0m in cash and cash equivalents. The group completed a share issue and a directed share issue during the second quarter 2020 and received in total, SEK 141.0m before transaction costs was contributed to the group. During the fourth quarter the group completed a directed share issue and received in total SEK 66m before transaction costs.

During 2021, management estimate that expenses for market initiatives in the USA will result in increased expenses while costs in the European operations are at the same level as 2020.

### Note 5 Segment information

An operating segment is an identified part of a group that engages in business activities from which it may earn revenues and incur expenses for which discrete financial information is available. An operating segment's results are reviewed regularly by the entity's chief operating decision maker to make decisions about resources to be allocated to the segment and assess its short- and long-term financial performance. Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker, The Chief Executive Officer and Group CEO, who is responsible for allocation resources and assess the performance of the operating segments, represents the chief operating decision maker who is responsible for strategic decisions. All Episurf Medical's revenues are generated from western Europe and all revenues are derived from one product (Episealer®) and from customers which are comparable. Even though Episurf Medical's revenues are generated from various countries in western Europe. Episurf Medical has grouped all such revenues into one reporting segment due to the similarities. The consolidated profit and loss statement, balance sheet and cash flow statements include information about the group's revenue and profitability development as well as financial position. The majority of the Group's fixed assets are attributable to Sweden.

At present, operations are monitored for the Group and the Parent Company as a whole.

### Note 6 Operating income

The Group's net sales of SEK 5.0m (4.9) refer primarily to sales of the Episurf Medical products Episealer® Condyle Solo, Episealer® Trochlea Solo and Episealer® Femoral Twin. The Parent Company's net sales of SEK 0.5m (0.6) refer to intra-group sales. Other income consists of a non-recurring income from a license agreement of SEK 1.5m for the µiFidelity® software platform and exchange rate gains.

#### Net sales per country

| mSEK                              | 2020       | 2019       |
|-----------------------------------|------------|------------|
| Germany                           | 3.9        | 3.4        |
| Sweden                            | 0.1        | 0.2        |
| Other countries in Europe         | 1.0        | 1.3        |
| Other countries outside of Europe | 0.0        | -          |
| <b>Total net sales</b>            | <b>5.0</b> | <b>4.9</b> |

#### Other operating income

| Group                               | 2020       | 2019       |
|-------------------------------------|------------|------------|
| License fee µiFidelity®             | 1.5        | -          |
| Other                               | 0.5        | 0.5        |
| <b>Total other operating income</b> | <b>2.0</b> | <b>0.5</b> |

| <b>Parent Company</b>               | <b>2020</b> | <b>2019</b> |
|-------------------------------------|-------------|-------------|
| License fee µiFidelity®             | 1.5         | -           |
| Other                               | 0.0         | 0.0         |
| <b>Total other operating income</b> | <b>1.5</b>  | <b>0.0</b>  |

## Note 7 Financial income and expenses

The year's financial income and expenses consist of exchange rate differences, interest income and interest expenses related to assets and liabilities measured at amortised cost. The year's interest income is attributable to bank accounts with credit institutions and expenses to the Groups Financing agreement.

During 2019 the Group and the Parent Company has taken a cost of SEK 0.7m, which relates to the termination of the financing agreement with European Select Growth Opportunities Fund, that the company has terminated.

## Note 8 Other external expenses

Other external expenses in the Group and the Parent Company are mainly attributable to increased investments in the controlled product launch and continued research and development-related costs.

### Audit fees

Auditing services refer to auditing of the annual report, the accounts and the administration by the Board of Directors and the President, other tasks incumbent upon the company's auditor and advice or other assistance arising from observations in connection with such examination or the performance of such other tasks. All other services are classified as other assignments.

| <b>Group</b>            | <b>2020</b> | <b>2019</b> |
|-------------------------|-------------|-------------|
|                         | <b>KPMG</b> | <b>KPMG</b> |
| Audit assignments       | 1.2         | 1.0         |
| Other advisory services | 0.0         | 0.1         |
| <b>Total</b>            | <b>1.2</b>  | <b>1.1</b>  |

| <b>Other auditors</b> | <b>2020</b> | <b>2019</b> |
|-----------------------|-------------|-------------|
| Audit assignments     | 0.1         | 0.1         |
| <b>Total</b>          | <b>0.1</b>  | <b>0.1</b>  |

| <b>Parent Company</b>   | <b>2020</b> | <b>2019</b> |
|-------------------------|-------------|-------------|
|                         | <b>KPMG</b> | <b>KPMG</b> |
| Audit assignments       | 1.2         | 0.9         |
| Other advisory services | 0.0         | 0.1         |
| <b>Total</b>            | <b>1.2</b>  | <b>1.0</b>  |

## Note 9 Employees and personnel costs

| <b>Personnel costs</b>                        |             |             |
|-----------------------------------------------|-------------|-------------|
| <b>Group</b>                                  | <b>2020</b> | <b>2019</b> |
| Remuneration                                  |             |             |
| Salary and other remuneration                 | 20.4        | 20.6        |
| Social security expenses                      | 6.1         | 5.5         |
| Pension expenses - defined contribution plans | 1.7         | 1.8         |
| Other                                         | 0.1         | 0.2         |
| <b>Total</b>                                  | <b>28.3</b> | <b>28.1</b> |
| <b>Parent Company</b>                         | <b>2020</b> | <b>2019</b> |
| Remuneration                                  |             |             |
| Salary and other remuneration                 | 9.6         | 8.9         |

|                                               |             |             |
|-----------------------------------------------|-------------|-------------|
| Social security expenses                      | 3.1         | 2.7         |
| Pension expenses - defined contribution plans | 1.0         | 0.9         |
| Other                                         | 0.0         | 0.1         |
| <b>Total</b>                                  | <b>13.7</b> | <b>12.6</b> |

For salary and remuneration to the CEO, management and Board of Directors, see Note 22.

#### Average number of employees

| Group         | 2020                     |             | 2019                     |             |
|---------------|--------------------------|-------------|--------------------------|-------------|
|               | Average no. Of employees | Of whom men | Average no. Of employees | Of whom men |
| Sweden        | 18                       | 10          | 18                       | 9           |
| Great Britain | 2                        | 1           | 2                        | 1           |
| Germany       | 5                        | 4           | 5                        | 4           |

| Parent Company | 2020                     |             | 2019                     |             |
|----------------|--------------------------|-------------|--------------------------|-------------|
|                | Average no. Of employees | Of whom men | Average no. Of employees | Of whom men |
| Sweden         | 13                       | 6           | 12                       | 4           |

#### Gender distribution of Board members and other senior executives

| Group and Parent Company              | 2020                     |             | 2019                     |             |
|---------------------------------------|--------------------------|-------------|--------------------------|-------------|
|                                       | Average no. Of employees | Of whom men | Average no. Of employees | Of whom men |
| Board members                         | 5                        | 4           | 5                        | 4           |
| CEO and senior executives             | 4                        | 2           | 5                        | 3           |
| <b>Total Group and Parent Company</b> | <b>9</b>                 | <b>6</b>    | <b>10</b>                | <b>7</b>    |

#### Incentive programmes

##### Employee stock option and Warrant programme 2020

The Annual General Meeting held on 2 April 2020, resolved to implement an employee stock option and warrant programme for the group's employees. The employee stock option and warrant programme included the management team and employees in the Episurf group. No more than 220,000 warrants of series 2020/2023(A) and 5,699,939 employee stock options, which consist of employee stock options and performance options (which were hedged by an issue of the same number of warrants of series 2020/2023(B) to the subsidiary Episurf Operations AB) were issued.

Each employee of the Episurf group (22 persons) shall be entitled to subscribe for up to 10,000 Incentive Warrants (i.e. a total of up to 220,000 Incentive Warrants may be issued).

The Stock Options shall be allocated in accordance with the following. Each employee of the Episurf group (22 persons) is proposed to be allotted, free of charge:

- 100,000 Stock Options (i.e. a total of 2,200,000 Stock Options); and
- four (4) Stock Option for each Incentive Warrant subscribed for in accordance with the above (i.e. a maximum of up to 880,000 Stock Options may be issued).

The Performance Options are proposed to be allotted to the participants free of charge in accordance with the following.

- the CEO is allotted 756,942 performance options;
- the other members of the senior management (four persons) are allotted 1,416,647 Performance Options in total, of which no participant within this category may be allotted more than 385,989 Performance Options; and
- the other participants (nine persons) are allotted 446,350 Performance Options in total, of which no participant within this category may be allotted more than 66,814 Performance Options.

Provided that the participant is still employed by the Episurf group at the exercise of the employee stock options, each option entitles the employee to purchase 1 share of series B in the Company during the period from and including 1 June 2023 until and including 31 May 2024 for a price of SEK 1.73.

As per the date of this Annual Report, the company has allotted a total of 2 931 200 employee stock, 2,619,939 performance options and 182,800 warrants.

The degree of fulfillment of the performance targets for the cash-based incentive program in 2020 determines how employees shall have the right to retain and exercise the granted performance options to acquire B shares

in the Company after the end of a three-year vesting period. Performance targets include (i) sales growth in Episurf's core markets, (ii) the increase in the number of clinical publications available for the Company's Episealer® technology, and (iii) the degree of progress in the clinical trials sponsored by the Company.

| <b>Changes in outstanding stock options</b> | <b>2020</b>      |
|---------------------------------------------|------------------|
| Granted                                     | 5,551,139        |
| Expired                                     | -                |
| <b>Amount at end of year</b>                | <b>5,551,139</b> |

| <b>Input information</b> | <b>Grant date</b> |
|--------------------------|-------------------|
| Calculation model        | Black-Scholes     |
| Share price              | 1.50              |
| Subscription price       | 1.73              |
| Grant date               | 2020-04-02        |
| Vesting date             | 2023-05-31        |
| Expected dividend        | -                 |
| Risk free interest rate  | -0.341            |
| Expected volatility*     | 60%               |
| Fair value per option    | 0.354             |

\* Volatility is calculated using share price data for the EPIS B share and verified with Bloomberg's external data sources.

|                                                                             | <b>31 Dec 2020</b> |
|-----------------------------------------------------------------------------|--------------------|
| Total expense recognized during the year, including social security charges | 1.4                |
| <b>Debt, end of December, social security charges</b>                       | <b>0.6</b>         |

#### **Employee stock option and Warrant programme 2018**

The Annual General Meeting held on 9 April 2018, resolved to implement an employee stock option and warrant programme for the group's employees. The employee stock option and warrant programme included the management team (excluding the CEO and COO who have chosen not to participate) and employees in the Episurf group. No more than 68,500 warrants of series 2018/2021(A) and 253,500 employee stock options (which were hedged by an issue of the same number of warrants of series 2018/2021(B) to the subsidiary Episurf Operations AB) were issued.

The warrants of series 2018/2021(A) were allocated in accordance with the following: (i) the four members of the senior management (excluding the CEO and COO) were entitled to subscribe for a total of up to 38,000 warrants (of which not more than 15,000 warrants were subscribed for by a sole participant), and (ii) the other participants (19 persons) were entitled to subscribe for a total of 30,500 warrants (of which not more than 10,000 warrants was subscribed for by a sole participant).

The employee stock options were allocated in accordance with the following: (i) the four members of the senior management (excluding the CEO and COO) are allotted a total of up to 75,000 employee stock options free of charge (of which not more than 30,000 employee stock options were allotted to a sole participant), and (ii) the other participants (19 persons) are allotted a total of up to 178,500 employee stock options free of charge (of which not more than 15,000 employee stock options may be allotted to a sole participant).

Provided that the participant is still employed by the Episurf group at the exercise of the employee stock options, each option entitles the employee to purchase 1.14 shares of series B (Adjusted from 1.00 to 1.14 in connection with the rights issue during 2019, the rights issue 2020 does not entail any adjustments.) in the Company during the period from and including 1 June 2021 until and including 31 May 2022 for a price of SEK 6.63.

As per the date of this Annual Report, the company has allotted a total of 207,500 employee stock and 68,500 warrants.

| <b>Changes in outstanding stock options</b> | <b>2020</b>    | <b>2019</b>    |
|---------------------------------------------|----------------|----------------|
| Granted                                     | 210,000        | 232,500        |
| Expired                                     | -2,500         | -22,500        |
| <b>Amount at end of year</b>                | <b>207,500</b> | <b>210,000</b> |

| <b>Input information</b> | <b>Grant date</b> |
|--------------------------|-------------------|
| Calculation model        | Black-Scholes     |
| Share price              | 6.02              |
| Subscription price*      | 6.63              |
| Grant date               | 2018-04-09        |
| Vesting date             | 2021-05-31        |
| Expected dividend        | -                 |
| Risk free interest rate  | -0.020            |
| Expected volatility**    | 30%               |
| Fair value per option    | 0.96              |

\*Adjusted from 7.53 to 6.63 in connection with the rights issue during 2019, the rights issue 2020 does not entail any adjustments.

\*\* Volatility is calculated using share price data for the EPIS B share and verified with Bloomberg's external data sources.

|                                                                             | <b>31 Dec 2020</b> | <b>31 Dec 2019</b> |
|-----------------------------------------------------------------------------|--------------------|--------------------|
| Total expense recognised during the year, including social security charges | 0.1                | 0.1                |
| <b>Debt, end of December, social security charges</b>                       | <b>0.0</b>         | <b>-</b>           |

### **Employee stock option and Warrant programme 2017**

The Annual General Meeting held on 22 May 2017, resolved to implement an employee stock option and warrant programme for the group's employees. The employee stock option and warrant programme included all employees in the group and comprised no more than 117.400 warrants of series 2017/2020(A) and no more than 513.700 employee stock options (which were hedged by an issue of the same number of warrants of series 2017/2020(B) to the subsidiary Episurf Operations AB).

The warrants of series 2017/2020(A) was allocated to the participants in the programme for a price of SEK 0.95 (corresponding to the market value) in accordance with the following: (i) the acting CEO was entitled to subscribe for up to 15.000 warrants; (ii) the other four members of the senior management was entitled to subscribe for 8.000 warrants each; and (iii) the other 22 participants was entitled to subscribe for 3.200 warrants each.

The employee stock options were allocated in accordance with the following: Each participant was proposed to be allotted, free of charge: (i) 6.000 employee stock options (except the acting CEO, who is allotted 10.000 employee stock options), plus (ii) 350 employee stock options per month he or she has been employed by the group, plus (iii) one employee stock options for each warrant subscribed for.

Provided that the holder is still employed by the group at the exercise of the options, each employee stock option entitles the employee to purchase 1,14 shares of series B (Adjusted from 1.00 to 1.14 in connection with the rights issue during 2019, the rights issue 2020 does not entail any adjustments.) in Episurf Medical during the period 1 June 2020 – 31 May 2021 for a price of SEK 7.53.

Each warrants of series 2017/2020(A) entitles its holder to subscribe for 1,14 shares of series B in Episurf Medical during the period 1 June 2020 – 31 May 2021 for a price of SEK 7.53.

As per the date of this Annual Report, the company has allotted a total of 293.025 employee stock and 117.400 warrants.

| <b>Changes in outstanding stock options</b> | <b>2020</b>    | <b>2019</b>    |
|---------------------------------------------|----------------|----------------|
| Opening balance                             | 293,025        | 432,825        |
| Granted                                     | -              | -              |
| Expired                                     | -13,750        | -139,780       |
| <b>Amount at end of year</b>                | <b>279.275</b> | <b>293,025</b> |

| <b>Input information</b> | <b>Grant date</b> |
|--------------------------|-------------------|
| Calculation model        | Black-Scholes     |
| Share price              | 6.45              |
| Subscription price*      | 7.53              |
| Grant date               | 2017-05-22        |
| Vesting date             | 2020-05-31        |
| Expected dividend        | -                 |
| Risk free interest rate  | -0.133            |
| Expected volatility**    | 30%               |
| Fair value per option    | 0.93              |

\*Adjusted from 8.55 to 7.53 in connection with the rights issue during 2019, the rights issue 2020 does not entail any adjustments.

\*\* Volatility is calculated using share price data for the EPIS B share and verified with Bloomberg's external data sources.

|                                                                             | 31 Dec 2020 | 31 Dec 2019 |
|-----------------------------------------------------------------------------|-------------|-------------|
| Total expense recognised during the year, including social security charges | -0.0        | 0.0         |
| <b>Debt, end of December, social security charges</b>                       | <b>-</b>    | <b>0.0</b>  |

#### Employee stock option programme 2016

The extraordinary general meeting held on 18 August 2016, resolved to implement an employee stock option programme for the senior management and certain other employees of the company. The Employee Stock Option Programme meant that the participants were allotted a certain number of employee stock options free of charge. The program expired in 2020, and no costs were incurred during the year.

| Changes in outstanding stock options | 2020     | 2019          |
|--------------------------------------|----------|---------------|
| Opening balance                      | 60,500   | 96,400        |
| Granted                              | -        | -             |
| Expired                              | -60,500  | -35,900       |
| <b>Amount at end of year</b>         | <b>-</b> | <b>60,500</b> |

#### Deferred cash bonus 2016

In connection with the extra ordinary general meetings, held on 18 August 2016, resolution on the implement of the Employee Stock Option Programme, the board of directors of Episurf Medical resolved to offer certain employees a deferred cash bonus. The program expired in 2020, and no costs were incurred during the year.

| Change cash bonus            | 2020     | 2019         |
|------------------------------|----------|--------------|
| Opening balance              | 6,000    | 12,000       |
| Granted                      | -        | -            |
| Expired                      | -6,000   | -6,000       |
| <b>Amount at end of year</b> | <b>-</b> | <b>6,000</b> |

#### Note 10 Income tax

The difference between the reported income tax expense and calculated income tax expense based on the applicable tax rate is as follows:

| Group                                                                  | 2020       | 2019       |
|------------------------------------------------------------------------|------------|------------|
| Profit before tax                                                      | -63.9      | -69.8      |
| Income tax calculated at the Group's applicable tax rate. 21.4%*       | 13.7       | 14.9       |
| Income that is exempt from taxation                                    | 0.0        | 0.0        |
| Expenses not deductible for tax purposes                               | -0.1       | -0.2       |
| The year's tax loss carryforward not recognised as deferred tax assets | 13.5       | 14.7       |
| <b>Income tax expense</b>                                              | <b>0.0</b> | <b>0.0</b> |

\*The corporate tax rate has changed from 22% to 21.4%. The tax rate in Sweden will be reduced to 20.6% in 2021.

At 31 December 2020 (2019) the Group had loss carry forwards amounting to SEK 443.5m (377.3), which have not been capitalised as deferred tax assets.

| Parent Company                                                         | 2020     | 2019     |
|------------------------------------------------------------------------|----------|----------|
| Profit before tax                                                      | -36.8    | -40.9    |
| Income tax calculated at the Group's applicable tax rate, 21.4%*       | 7.9      | 8.8      |
| Income that is exempt from taxation                                    | 0.0      | -        |
| Expenses not deductible for tax purposes                               | -0.0     | -0.1     |
| The year's tax loss carryforward not recognised as deferred tax assets | 7.9      | 8.6      |
| <b>Income tax expense</b>                                              | <b>-</b> | <b>-</b> |

\*The corporate tax rate has changed from 22% to 21.4%. The tax rate in Sweden will be reduced to 20.6% in 2021.

At 31 December 2020 (2019) the Parent Company had loss carry forwards amounting to SEK 280.4m (243.6), which have not been capitalised as deferred tax assets.

## Note 11 Intangible assets

| <b>Group</b>                                                     | <b>31 Dec 2020</b> | <b>31 Dec 2019</b> |
|------------------------------------------------------------------|--------------------|--------------------|
| <b>Patents</b>                                                   |                    |                    |
| Opening cost                                                     | 30.2               | 25.9               |
| Purchases                                                        | 3.5                | 4.4                |
| Sales and disposals                                              | -0.5               | -                  |
| <b>Closing accumulated cost</b>                                  | <b>33.3</b>        | <b>30.2</b>        |
| Opening depreciation                                             | -16.8              | -14.2              |
| The year's depreciation                                          | -2.6               | -2.5               |
| Sales and disposals                                              | 0.2                | -                  |
| <b>Closing accumulated depreciation</b>                          | <b>-19.1</b>       | <b>-16.8</b>       |
| <b>Closing carrying amount</b>                                   | <b>14.1</b>        | <b>13.5</b>        |
| <b>Development expenses</b>                                      |                    |                    |
| Closing cost                                                     | 14.4               | 13.3               |
| The year's capitalisation                                        | 1.1                | 1.1                |
| <b>Closing accumulated cost</b>                                  | <b>15.5</b>        | <b>14.4</b>        |
| Opening depreciation                                             | -6.4               | -3.9               |
| The year's depreciation                                          | -2.4               | -2.6               |
| <b>Closing accumulated depreciation</b>                          | <b>-8.9</b>        | <b>-6.4</b>        |
| <b>Closing carrying amount</b>                                   | <b>6.7</b>         | <b>8.0</b>         |
| <b>Closing carrying amount, patents and development expenses</b> | <b>20.8</b>        | <b>21.5</b>        |
| <b>Parent Company</b>                                            |                    |                    |
| <b>Development expenses</b>                                      | <b>31 Dec 2020</b> | <b>31 Dec 2019</b> |
| Opening cost                                                     | 14.4               | 13.3               |
| The year's capitalisation                                        | 1.1                | 1.1                |
| <b>Closing accumulated cost</b>                                  | <b>15.5</b>        | <b>14.4</b>        |
| Opening depreciation                                             | -6.4               | -3.9               |
| The year's depreciation                                          | -2.4               | -2.6               |
| <b>Closing accumulated depreciation</b>                          | <b>-8.9</b>        | <b>-6.4</b>        |
| <b>Closing carrying amount, development expenses</b>             | <b>6.7</b>         | <b>8.0</b>         |

## Note 12 Property, plant and equipment

| <b>Group</b>                            | <b>31 Dec 2020</b> | <b>31 Dec 2019</b> |
|-----------------------------------------|--------------------|--------------------|
| Opening cost                            | 1.0                | 1.0                |
| Purchases                               | -                  | -                  |
| Sales and disposals                     | -0.1               | -                  |
| <b>Closing accumulated cost</b>         | <b>0.8</b>         | <b>1.0</b>         |
| Opening depreciation                    | -0.9               | -0.9               |
| The year's depreciation                 | -0.0               | -0.0               |
| Sales and disposals                     | 0.1                | -                  |
| <b>Closing accumulated depreciation</b> | <b>-0.8</b>        | <b>-0.9</b>        |
| <b>Closing carrying amount</b>          | <b>0.0</b>         | <b>0.1</b>         |

| <b>Parent Company</b>                   | <b>31 Dec 2020</b> | <b>31 Dec 2019</b> |
|-----------------------------------------|--------------------|--------------------|
| Opening cost                            | 0.7                | 0.7                |
| Purchases                               | -                  | -                  |
| Sales and disposals                     | -0.1               |                    |
| <b>Closing accumulated cost</b>         | <b>0.7</b>         | <b>0.7</b>         |
| Opening depreciation                    | -0.7               | -0.7               |
| The year's depreciation                 | -0.0               | -0.0               |
| Sales and disposals                     | 0.1                | -                  |
| <b>Closing accumulated depreciation</b> | <b>-0.7</b>        | <b>-0.7</b>        |
| <b>Closing carrying amount</b>          | <b>0.0</b>         | <b>0.0</b>         |

### Note 13 Shares in group companies

| <b>Parent Company</b>          | <b>31 Dec 2020</b> | <b>31 Dec 2019</b> |
|--------------------------------|--------------------|--------------------|
| Opening cost                   | 137.4              | 106.8              |
| Investment                     | -                  | 0.1                |
| Capital infusion               | 25.5               | 30.5               |
| <b>Closing carrying amount</b> | <b>162.9</b>       | <b>137.4</b>       |

| <b>Name</b>                   | <b>Corporate identification</b> |                   | <b>% of capital</b> | <b>No. Of shares</b> | <b>Equity at 31 Dec 2020</b> | <b>Equity at 31 Dec 2019</b> |
|-------------------------------|---------------------------------|-------------------|---------------------|----------------------|------------------------------|------------------------------|
|                               | <b>no.</b>                      | <b>Domicile</b>   |                     |                      |                              |                              |
| Episurf IP-Management AB      | 556921-7747                     | Stockholm, Sweden | 100%                | 10 000               | 0.5                          | 0.1                          |
| Episurf Operation AB          | 556921-7739                     | Stockholm, Sweden | 100%                | 10 000               | 0.4                          | 0.7                          |
| Episurf Europe AB             | 556921-7721                     | Stockholm, Sweden | 100%                | 10 000               | 0.5                          | 1.8                          |
| Episurf UK Ltd                | 9 548 146                       | Lincoln, UK       | 100%                | 1                    | -1.3                         | -1.5                         |
| Episurf DE GmbH               | HRB 218113                      | München, Germany  | 100%                |                      | 0.1                          | -0.3                         |
| Episurf Medical Inc           | 34-408080832                    | Delaware, USA     | 100%                | 1 000                | 0.2                          | 0.1                          |
| Episurf India Private Limited | U74999DL2018FTC342052           | New Delhi, India  | 100%                | 100 000              | 0.1                          | 0.1                          |

During 2019, the company acquired 100% of Episurf India Private Limited's share capital. No other changes have occurred.

### Note 14 Long-term receivables

#### Long-term receivables from group companies

| <b>Parent Company</b>                                           | <b>31 Dec 2020</b> | <b>31 Dec 2019</b> |
|-----------------------------------------------------------------|--------------------|--------------------|
| Opening long-term receivables from group companies              | 20.0               | 24.0               |
| Repaid group companies                                          | -28.1              | -33.9              |
| Loan group companies                                            | 41.3               | 30.0               |
| <b>Total closing long-term receivables from group companies</b> | <b>33.2</b>        | <b>20.0</b>        |

#### Other non-current financial receivables

| <b>Parent Company</b>                                | <b>31 Dec 2020</b> | <b>31 Dec 2019</b> |
|------------------------------------------------------|--------------------|--------------------|
| Non-current licence revenue                          | 0.5                | -                  |
| <b>Total other non-current financial receivables</b> | <b>0.5</b>         | <b>-</b>           |

### Note 15 Trade receivables

The fair value of the Group's trade receivables corresponds to the carrying amount.

On the balance sheet date, trade payables amounting to SEK 0.6m (0.7) The company has written down SEK 0.0m (0.0) of the company's trade receivables.

| Group                               | 31 Dec 2020 | 31 Dec 2019 |
|-------------------------------------|-------------|-------------|
| Trade receivables                   | 0.6         | 0.7         |
| Less: provisions for doubtful debts | -0.0        | -0.0        |
| <b>Trade receivables, net</b>       | <b>0.6</b>  | <b>0.7</b>  |

#### Note 16 Inventories

| Group                                      | 31 Dec 2020 | 31 Dec 2019 |
|--------------------------------------------|-------------|-------------|
| <b>Cost of inventories</b>                 |             |             |
| Finished goods                             | 2.0         | 1.8         |
| <b>Total inventories before impairment</b> | <b>2.0</b>  | <b>1.8</b>  |

Inventories consist entirely of goods for resale. The inventories are not subject to obsolescence.

#### Note 17 Prepaid expenses and accrued income

| Group                                            | 31 Dec 2020 | 31 Dec 2019 |
|--------------------------------------------------|-------------|-------------|
| Prepaid rents*                                   | 0.0         | 0.1         |
| Accrued income                                   | -           | -           |
| Other items                                      | 1.9         | 1.0         |
| <b>Total prepaid expenses and accrued income</b> | <b>1.9</b>  | <b>1.1</b>  |

\*Prepaid lease refers to short-term leases.

| Parent Company                                   | 31 Dec 2020 | 31 Dec 2019 |
|--------------------------------------------------|-------------|-------------|
| Prepaid rents                                    | 0.4         | 0.4         |
| Other items                                      | 1.3         | 0.4         |
| <b>Total prepaid expenses and accrued income</b> | <b>1.7</b>  | <b>0.8</b>  |

#### Note 18 Share capital

The statement of changes in equity is found in the report, directly after the balance sheet.

|                                       | No. Of shares     | Share capital     |
|---------------------------------------|-------------------|-------------------|
| <b>Balance at 31 December 2018</b>    | <b>31,631,169</b> | <b>9 497 383</b>  |
| Directed share issue*                 | 3,290,210         | 987 898           |
| Rights-issue                          | 53,730,113        | 16 132 678        |
| Issue In-kind, for conversion of debt | 2,279,263         | 684 358           |
| <b>Balance at 31 December 2019</b>    | <b>90,930,755</b> | <b>27 302 317</b> |

\* The directed share issue that was completed in December 2018 was registered with the Swedish Companies Registration Office on January 9, 2019 and the company's shares and votes then increased by 3,290,210.

|                                       | No. Of shares      | Share capital     |
|---------------------------------------|--------------------|-------------------|
| <b>Balance at 31 December 2019</b>    | <b>90,930 755</b>  | <b>27,302,317</b> |
| Directed share issue                  | 59,999 999         | 18,015,236        |
| Rights-issue                          | 34,099 033         | 10,238,369        |
| Directed share issue                  | 36,811 000         | 11,052,648        |
| Issue In-kind, for conversion of debt | 199,756            | 59,978            |
| <b>Balance at 31 December 2020</b>    | <b>222,040,543</b> | <b>66,668,547</b> |

The shares have a quota value of SEK 0.30 each (0.30). Each class A share carries the right to three votes at a general meeting and each share of class B carries the right to one vote at a general meeting. Of the total number of 222,040,543 shares, 971,024 were class A shares and 221,069,519 were class B shares. All shares registered on the balance sheet date were fully paid-up.

#### Foreign currency translation reserve

Reserves consist of all exchange gains/losses arising on translation of the financial statements of foreign operations that present their financial statements in a currency other than that used by the Group. This includes foreign currency

differences on monetary items that are a receivable from or payable to a foreign operation, for which settlement is neither planned nor likely to occur in the foreseeable future.

#### Proposed appropriation of earnings

The Board of Directors proposes that the following earnings be at the disposal of the Annual General Meeting:

|                          |                    |
|--------------------------|--------------------|
| <b>SEK</b>               |                    |
| Share premium reserve    | 546,227,299        |
| Accumulated deficit      | -250,350,376       |
| <b>Loss for the year</b> | <b>-36,814,808</b> |
| <b>Total</b>             | <b>259,062,115</b> |

The Board proposes that the earnings be appropriated so that SEK 259,062,115 is carried forward to new account, of which SEK 546,227,299 to the share premium reserve and -287,165,184 to balanced earnings.

#### Note 19 Other liabilities

| <b>Group</b>                   | <b>31 Dec 2020</b> | <b>31 Dec 2019</b> |
|--------------------------------|--------------------|--------------------|
| Personnel-related liabilities  | 1.9                | 0.8                |
| Other                          | 0.3                | 0.4                |
| <b>Total other liabilities</b> | <b>2.3</b>         | <b>1.2</b>         |

| <b>Parent Company</b>          | <b>31 Dec 2020</b> | <b>31 Dec 2019</b> |
|--------------------------------|--------------------|--------------------|
| Personnel-related liabilities  | 1.4                | 0.4                |
| Other                          | 0.0                | 0.0                |
| <b>Total other liabilities</b> | <b>1.4</b>         | <b>0.4</b>         |

#### Note 20 Accrued expenses and deferred income

| <b>Group</b>                                      | <b>31 Dec 2020</b> | <b>31 Dec 2019</b> |
|---------------------------------------------------|--------------------|--------------------|
| Accrued personnel-related expenses                | 2.4                | 2.1                |
| Accrued Board fees                                | 0.2                | 0.3                |
| Accrued consulting fees                           | 1.2                | 0.8                |
| <b>Total accrued expenses and deferred income</b> | <b>3.8</b>         | <b>3.2</b>         |

| <b>Parent company</b>                             | <b>31 Dec 2020</b> | <b>31 Dec 2019</b> |
|---------------------------------------------------|--------------------|--------------------|
| Accrued personnel-related expenses                | 1.9                | 1.6                |
| Accrued Board fees                                | 0.2                | 0.3                |
| Accrued consulting fees                           | 1.0                | 0.4                |
| <b>Total accrued expenses and deferred income</b> | <b>3.1</b>         | <b>2.3</b>         |

#### Note 21 Leases

Future lease payments under cancellable operating leases fall due as follows:

| <b>Parent Company</b>       | <b>31 Dec 2020</b> | <b>31 Dec 2019</b> |
|-----------------------------|--------------------|--------------------|
| Within one year             | 1.8                | 1.7                |
| Between one and three years | 1.5                | 3.5                |
| Later than three years      | -                  | -                  |
| <b>Total obligations</b>    | <b>3.3</b>         | <b>5.2</b>         |

The notice period for these agreements varies between 12 months and 3 years

## Leases, group

| <b>Rights-of-use asset</b>                                             | <b>2020</b>        | <b>2019</b>        |
|------------------------------------------------------------------------|--------------------|--------------------|
| Depreciation for the year                                              | 2.3                | 2.3                |
| Interest rate for the year                                             | -0.3               | -0.3               |
| This year's cost for short-term leases                                 | -                  | -                  |
| This year's cost of contracts with leases of low value during the year | -                  | -0.0               |
| Total cash flow for leases during the year                             | 2.2                | 2.0                |
| <b>Addition for rights-of-use asset during the year</b>                | <b>2020</b>        | <b>2019</b>        |
| Premises                                                               | -                  | -                  |
| New cars                                                               | 0.2                | -                  |
| Extensions                                                             | -                  | -                  |
| <b>Total additions to rights-of-use asset</b>                          | <b>0.2</b>         | <b>-</b>           |
| <b>Value rights-of-use asset</b>                                       | <b>31 Dec 2020</b> | <b>31 Dec 2019</b> |
| Premises                                                               | 2.8                | 4.2                |
| New cars                                                               | 0.8                | 1.5                |
| Extensions                                                             | 0.2                | 0.2                |
| <b>Closing value rights-of-use asset</b>                               | <b>3.9</b>         | <b>5.9</b>         |
| <b>Lease liability</b>                                                 | <b>31 Dec 2020</b> | <b>31 Dec 2019</b> |
| Current lease liability                                                | 2.4                | 2.4                |
| Non-current lease liability                                            | 1.5                | 3.5                |
| <b>Closing value lease liability</b>                                   | <b>3.9</b>         | <b>5.8</b>         |

## Reconciliation of liabilities arising from financing activities – Group

| mSEK                                                           | 31 Dec<br>2019 | Cash-flow   | Non-cash changes               |                                    |                                 | 31 Dec<br>2020 |
|----------------------------------------------------------------|----------------|-------------|--------------------------------|------------------------------------|---------------------------------|----------------|
|                                                                |                |             | Acquisition of<br>subsidiaries | New/changed<br>lease<br>agreements | Exchange<br>rate<br>differences |                |
| Lease liability                                                | 5.8            | -2.2        | -                              | 0.2                                | -                               | 3.9            |
| <b>Total liabilities arising from<br/>financing activities</b> | <b>5.8</b>     | <b>-2.2</b> | <b>-</b>                       | <b>0.2</b>                         | <b>-</b>                        | <b>3.9</b>     |

| mSEK                                                               | 31 Dec<br>2018 | Cash-<br>flow | Non-cash changes                  |                      |                                 | 31 Dec<br>2019 |
|--------------------------------------------------------------------|----------------|---------------|-----------------------------------|----------------------|---------------------------------|----------------|
|                                                                    |                |               | Acquisition<br>of<br>subsidiaries | New lease agreements | Exchange<br>rate<br>differences |                |
| Lease liability                                                    | 7.8            | -2.0          | -                                 | -                    | --                              | 5.8            |
| <b>Total liabilities arising<br/>from financing<br/>activities</b> | <b>7.8</b>     | <b>-2.0</b>   | <b>-</b>                          | <b>-</b>             | <b>--</b>                       | <b>5.8</b>     |

## Note 22 Related party transactions

Shareholder and Board member Leif Ryd has received consulting fees for ongoing work as well as work for the Clinical Advisory Board during the financial year of SEK 0.6m (0.6). Board member Wilder Fulford has received consulting fees for ongoing project during the financial year of SEK 0.7 (0.4). The Chairman and Members of the board's fees were agreed by the AGM and is shown below. The Chairman, Dennis Stripe receive SEK 0.4m. Wilder Fulford, Laura Shunk and Christian Krüeger receive remuneration of SEK 0.2m. Leif Ryd receive remuneration of SEK 0.1m. In total, the board fees amount to SEK 1.1m (1.1). Variable remuneration is reported according to the decision of the Remuneration Committee. The Group has only defined contribution pension plans. The pension expense refers to the expense that has affected profit for the year. During the year, the CEO, Pål Ryfors, received 140,000 Employee stock options, 756,942 performance options and 10,000 warrants, other senior executives received 560,000 warrants, 1,416,647 warrants and 40,000 warrants. The company did not have an option program in 2019.

| <b>2020</b>                     | <b>Salary/fees</b> | <b>Variable remuneration</b> | <b>Other benefits</b> | <b>Pension expense</b> | <b>Other remuneration</b> | <b>Total</b> |
|---------------------------------|--------------------|------------------------------|-----------------------|------------------------|---------------------------|--------------|
| Board Chairman, Dennis Stripe   | 0.4                |                              |                       |                        |                           | <b>0.4</b>   |
| Board member, Laura Shunk       | 0.2                |                              |                       |                        |                           | <b>0.2</b>   |
| Board member, Leif Ryd          | 0.1                |                              |                       |                        | 0.6                       | <b>0.7</b>   |
| Board member, Christian Krüeger | 0.2                |                              |                       |                        |                           | <b>0.2</b>   |
| Board member, Wilder Fulford    | 0.2                |                              |                       |                        | 0.7                       | <b>0.9</b>   |
| CEO Pål Ryfors                  | 2.7                | 0.4                          | 0.1                   | 0.3                    |                           | <b>3.5</b>   |
| Other senior executives         | 2.8                | 0.3                          | 0.0                   | 0.7                    |                           | <b>3.8</b>   |
| <b>Total</b>                    | <b>6.6</b>         | <b>0.7</b>                   | <b>0.2</b>            | <b>1.0</b>             | <b>1.3</b>                | <b>9.8</b>   |

| <b>2019</b>                     | <b>Salary/fees</b> | <b>Variable remuneration</b> | <b>Other benefits</b> | <b>Pension expense</b> | <b>Other remuneration</b> | <b>Total</b> |
|---------------------------------|--------------------|------------------------------|-----------------------|------------------------|---------------------------|--------------|
| Board Chairman, Dennis Stripe   | 0.4                |                              |                       |                        |                           | <b>0.4</b>   |
| Board member, Laura Shunk       | 0.2                |                              |                       |                        |                           | <b>0.2</b>   |
| Board member, Leif Ryd          | 0.1                |                              |                       |                        | 0.6                       | <b>0.7</b>   |
| Board member, Christian Krüeger | 0.2                |                              |                       |                        |                           | <b>0.2</b>   |
| Board member, Wilder Fulford    | 0.2                |                              |                       |                        | 0.4                       | <b>0.6</b>   |
| CEO Pål Ryfors                  | 1.5                | 0.4                          | 0.1                   | 0.3                    |                           | <b>2.5</b>   |
| Other senior executives         | 3.9                | 0.3                          | 0.1                   | 0.8                    |                           | <b>5.1</b>   |
| <b>Total</b>                    | <b>6.6</b>         | <b>0.7</b>                   | <b>0.2</b>            | <b>1.1</b>             | <b>1.0</b>                | <b>9.6</b>   |

### Bonus

A bonus for 2020 will be paid to all of the company's employees based on the degree of goal fulfillment for annual goal for 2020.

### Termination benefits

Termination benefits Between the CEO Pål Ryfors and the company there is a mutual term of notice of 6 months. In the event that employment is terminated by the company, for reasons other than the CEO's breach of contract, the CEO has the right to termination benefits equal to six months' salary.

## Note 23 Significant events after the end of the financial year

- » Episurf Medical announced its intention to file a 510(k) application in the US for an Episealer® Patellofemoral System
- » First Episealer® Talus surgery in the Asia-Pacific region performed
- » New patents approved in Hong Kong and US for Episurf Medical
- » Episurf Medical entered into distribution agreement for Australia and New Zealand
- » Episealer®: Clinical results with 5-years' follow-up data will be presented at the 3rd World Arthroplasty Congress
- » Clinical results for Episealer® were accepted for presentation at the 19<sup>th</sup> ESSKA congress
- » Episurf Medical provided COVID-19 related update ahead of an investor conference

#### Note 24 Pledged assets

| <b>Group and parent company</b> | <b>31 Dec 2020</b> | <b>31 Dec 2019</b> |
|---------------------------------|--------------------|--------------------|
| Rent deposit                    | 0.3                | 0.3                |
| <b>Total pledged assets</b>     | <b>0.3</b>         | <b>0.3</b>         |

The group and parent company's pledged assets amount to SEK 0.3m (0.3) and is comprised of restricted security deposits for the office lease.

## Statement of assurance

The Board of Directors and CEO affirm that the Annual Report for the parent company has been prepared in accordance with generally accepted accounting principles in Sweden and the consolidated financial statements have been prepared in accordance with International Accounting Standards as prescribed by the European Parliament and Regulation (EC) 1606/2002 dated July 19, 2002 on the application of International Accounting Standards. The Parent Company financial statements and the consolidated financial statements give a true and fair view of the Parent Company's and the Group's financial position and results of operations. The administration report for the Parent Company and the Group provides a true and fair view of the development of the Parent Company and Group's business activities, financial position and results of operations as well as the significant risks and uncertainties the Parent Company and its subsidiaries are exposed to.

The Annual Report for the Parent Company and the Group referred to above was approved by the Board of Directors and CEO on March 30, 2021. The Consolidated income statement and balance sheet and the Parent Company's income statement and balance sheet are subject to approval by the Annual General Meeting of the shareholders on May 10, 2021.

Stockholm, March 30, 2021

Dennis Stripe  
Board Chairman

Wilder Fulford  
Board member

Christian Krüeger  
Board member

Leif Ryd  
Board member

Laura Shunk  
Board member

Pål Ryfors  
CEO

Our auditor's report was submitted on March 30, 2021  
KPMG AB

Duane Swanson  
Authorised Public Accountant



## Auditor's Report

To the general meeting of the shareholders of Episurf Medical AB (publ), corp. id 556767-0541

### Report on the annual accounts and consolidated accounts

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#### Opinions

We have audited the annual accounts and consolidated accounts of Episurf Medical AB (publ) for the year 2020, except for the corporate governance statement on pages 43-54. The annual accounts and consolidated accounts of the company are included on pages 32-42 and 56-84 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act, and present fairly, in all material respects, the financial position of the parent company as of 31 December 2020 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of 31 December 2020 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. Our opinions do not cover the corporate governance statement on pages 43-54. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the group.

Our opinions in this report on the the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the parent company's Board of directors in accordance with the Audit Regulation (537/2014) Article 11.

#### Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

#### Key Audit Matters

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and consolidated accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters.

#### Shares in group companies

See note 13 and accounting principles on page 70 in the annual account and consolidated accounts for detailed information and description of the matter.

##### Description of key audit matter

The carrying value at 31 December 2020 for shares in group companies totaled 162.9 MSEK for the parent company and are subject to an impairment test.

The impairment test of these assets are dependent management's estimates and judgments of future revenues and operating results as well as required levels of working capital and investments. Another important assumption is which discount rate to be used in order to reflect the time value of money as well as the specific risks the operations face.

##### Response in the audit

We have assessed whether the impairment test for shares in group companies have been prepared in accordance with the prescribed method as well as assessed the reasonableness in the group's test of the carrying value of the shares in group companies.

Moreover, we have considered the reasonableness of the predicted future cash flows as well as the discount rates used through evaluation of the group's written documentation and forecasts. We have also performed sensitivity analysis to evaluate how reasonable changes in the assumptions may impact the valuation.

### Other Information than the annual accounts and consolidated accounts

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This document also contains other information than the annual accounts and consolidated accounts and is found on pages 2-31, 43-54 and 89-92. The other information comprises also of the remuneration report which we obtained prior to the date of this auditor's report. The Board of Directors and the Chief Executive Officer are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

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## Responsibilities of the Board of Directors and the Chief Executive Officer

The Board of Directors and the Chief Executive Officer are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the Chief Executive Officer are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts The Board of Directors and the Chief Executive Officer are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Chief Executive Officer intend to liquidate the company, to cease operations, or has no realistic alternative but to do so.

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## Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Chief Executive Officer.

- Conclude on the appropriateness of the Board of Directors' and the Chief Executive Officer's, use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions.

- We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

We must also provide the Board of Directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, measures that have been taken to eliminate the threats or related safeguards.

From the matters communicated with the Board of Directors, we determine those matters that were of most significance in the audit of the annual accounts and consolidated accounts, including the most important assessed risks for material misstatement, and are therefore the key audit matters. We describe these matters in the auditor's report unless law or regulation precludes disclosure about the matter.

## Report on other legal and regulatory requirements

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### Opinions

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Chief Executive Officer of Episurf Medical AB (publ) for the year 2020 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Chief Executive Officer be discharged from liability for the financial year.

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### Basis for Opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

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### Responsibilities of the Board of Directors and the Chief Executive Officer

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial

situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner.

The Chief Executive Officer shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

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### Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Chief Executive Officer in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give

rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional scepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

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### The auditor's examination of the corporate governance statement

The Board of Directors is responsible for that the corporate governance statement on pages 43-54 has been prepared in accordance with the Annual Accounts Act.

Our examination of the corporate governance statement is conducted in accordance with FAR's auditing standard RevR 16 The auditor's examination of the corporate governance statement. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2-6 of the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the other parts of the annual accounts and consolidated accounts and are in accordance with the Annual Accounts Act.

KPMG AB, Box 382, 101 27, Stockholm, was appointed auditor of Episurf Medical AB (publ) by the general meeting of the shareholders on the 2 april 2020. KPMG AB or auditors operating at KPMG AB have been the company's auditor since 2015.

Stockholm 30 March 2021

KPMG AB

Duane Swanson

Authorized Public Accountant

## Definitions

**Financial definitions:** Reference is made in the Annual Report to a number of financial performance measures which are not defined according to IFRS. These performance measures provide complementary information and are used to help investors as well as group management analyse the company's operations and facilitate an evaluation of the performance. Since not all companies calculate financial performance measures in the same manner, these are not always comparable with measures used by other companies. These financial performance measures should therefore not be regarded as a replacement for measures as defined according to IFRS.

**Average number of shares outstanding:** The weighted average number of shares outstanding before or after dilution.

**Debt ratio:** Shareholders' equity divided by total assets at end of period.

**Equity per share:** Shareholders' equity at end of period divided by number of shares outstanding at period end.

**Loss per share:** Profit for the period attributable to owners of the parent divided by the average number of shares outstanding.



## Glossary

|                                                    |                                                                                                                                                                                                                                 |
|----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Arthritis:</b>                                  | See Osteoarthritis.                                                                                                                                                                                                             |
| <b>Arthroscopy:</b>                                | Inspection of the inside of a joint with the help of an arthroscope. An instrument is introduced through a small cut to investigate the inside of the joint and possibly correct any problems (a type of keyhole surgery).      |
| <b>Cartilage:</b>                                  | Shock absorbing and friction reducing tissue. This tissue that covers the end of bones and allows movement with low friction.                                                                                                   |
| <b>Cartilage defect of grade III (ICRS scale):</b> | Defect extending down to >50% of the cartilage depth.                                                                                                                                                                           |
| <b>Cartilage defect of grade IV (ICRS scale):</b>  | Lesion through the cartilage, into the bone.                                                                                                                                                                                    |
| <b>CE marking:</b>                                 | A CE mark means that the manufacturer or importer has the formal approvals necessary to market and sell the product in the European Economic Area.                                                                              |
| <b>Clinical results:</b>                           | Outcome from clinical treatment of humans, where parameters such as efficacy and safety are evaluated.                                                                                                                          |
| <b>Cobalt chrome:</b>                              | A metal alloy mainly consisting of cobalt and chromium, commonly occurring in metal alloys used in knee prostheses.                                                                                                             |
| <b>Debridement:</b>                                | Removal of damaged tissue.                                                                                                                                                                                                      |
| <b>Degenerative origin:</b>                        | Conditions in which the cells, tissues or organs deteriorate and lose function. In degenerative joint disease, the deterioration is due to wear, tear or breakdown of cartilage.                                                |
| <b>FDA:</b>                                        | US Food and Drug Administration.                                                                                                                                                                                                |
| <b>Focal cartilage defect:</b>                     | A cartilage defect in a well-defined area.                                                                                                                                                                                      |
| <b>Femoral condyles:</b>                           | Two bony protuberances on the thighbone side of the knee joint that articulate with the shinbone. The name originates from the anatomical terms femur (thighbone) and condyle (articular head).                                 |
| <b>Gross order intake:</b>                         | Gross order intake represents the aggregated value of Episealer® orders received and approved by responsible surgeon during the relevant period.                                                                                |
| <b>Hydroxyapatite:</b>                             | A mineral that is the major component of human bone tissue and the main mineral of dental enamel and dentin.                                                                                                                    |
| <b>Invasive treatment alternative:</b>             | Treatments that require a surgical procedure.                                                                                                                                                                                   |
| <b>Micro fracturing:</b>                           | A biological surgical technique that can be used in treatment of focal cartilage defects (not extensive osteoarthritis) in an attempt to stimulate the growth of new cartilage.                                                 |
| <b>MRI:</b>                                        | Magnetic resonance imaging, a medical imaging technique where images acquired using a strong magnetic field allows the user to get three-dimensional image data of the patient.                                                 |
| <b>OA:</b>                                         | See osteoarthritis.                                                                                                                                                                                                             |
| <b>Order backlog:</b>                              | Order backlog represents all orders that have been booked but where no revenue has been recognised.                                                                                                                             |
| <b>Orthopaedics:</b>                               | The medical specialty that focuses on injuries and diseases of the body's musculoskeletal system. This complex system includes bones, Joints, ligaments, tendons, muscles and nerves.                                           |
| <b>Osteoarthritis:</b>                             | A type of joint disease that is characterised by loss of joint function with varying destruction of joint cartilage and the underlying bone.                                                                                    |
| <b>Osteochondral defect:</b>                       | Cartilage and underlying bone defect.                                                                                                                                                                                           |
| <b>Prosthesis:</b>                                 | An artificial device that replaces a missing or injured body part, such as artificial arm or leg. The term prosthesis is also used for certain of the implants that are used to repair joints, such as hip and knee prostheses. |

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|--------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Reimbursement:</b>    | Reimbursement is a word that is used generally in the healthcare industry to describe the payment systems that apply to healthcare costs in various countries.                                                                                 |
| <b>TKA:</b>              | Total knee arthroplasty, total knee joint replacement, which is a surgical procedure primarily used to relieve arthritis in which the knee joint is replaced with artificial parts (prostheses).                                               |
| <b>Traumatic damage:</b> | Damage caused by an outside force, such as fall injuries.                                                                                                                                                                                      |
| <b>UKA:</b>              | Unicompartmental knee arthroplasty, partial knee joint replacement which is a surgical procedure primarily used to relieve arthritis in one of the knee compartments. Parts of the knee joint are replaced with artificial parts (prostheses). |

## Annual General Meeting

**EPISURF MEDICAL AB (PUBL)** will hold its Annual General Meeting on Monday, May 10, 2021. To counteract the spread of covid-19, the Board has decided that the meeting shall be conducted without the physical presence of shareholders, proxies, or outsiders. The shareholders before the meeting shall have the opportunity to exercise their voting rights by postal vote.

Notice of the Annual General Meeting will be made via Episurf Medical's website [www.episurf.com](http://www.episurf.com) and through advertising in the Official Gazette (Post- och Inrikes Tidningar), where the Annual General Meeting agenda will appear. Information that a summons has been issued takes place through advertising in Dagens Industri. The nominating committee ahead of the AGM consists of Dennis Stripe (Chairman of Episurf Medical AB), Leif Ryd (representing Niles Noblitt), Robert Charpentier (representing Carl Palmstierna) and Max Mennfort (representing Pål Ryfors). The Chairman of the Nomination Committee is Robert Charpentier.

### Exercise of voting rights at the meeting

Prior to the Annual General Meeting, shareholders will have the opportunity to exercise their voting rights by post. To exercise its voting rights at the meeting, the shareholder must be entered as a shareholder in the share register kept by Euroclear Sweden AB on Friday, April 30, 2021, or, if the shares are nominee-registered, request that the nominee register the shares at such time that the registration is effected on Tuesday, May 4, 2021, and have cast their postal vote in accordance with the instructions in the notice convening the Annual General Meeting so that the postal vote is received by the Company no later than Friday, May 7, 2021.

### Financial calendar

|                                           |                  |
|-------------------------------------------|------------------|
| <b>Interim Report January-March</b>       | 29 April 2021    |
| <b>AGM</b>                                | 10 May 2021      |
| <b>Interim Report April-June 2021</b>     | 16 July 2021     |
| <b>Interim Report July-September 2021</b> | 29 October 2021  |
| <b>Year-End Report 2021</b>               | 11 February 2022 |

Financial reports and issued press releases are available from the date of publication on Episurf Medical's website [www.episurf.com](http://www.episurf.com). Episurf Medical has of environmental and cost reasons chosen not to print the annual report. A printed version of the annual report will be distributed to shareholders and others who made such request. The annual report can also be ordered from Episurf Medical on the following address: Karlavägen 60, SE-114 49, Stockholm, Sweden.

### IR-contact



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