

Episurf Medical



Annual Report 2018

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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

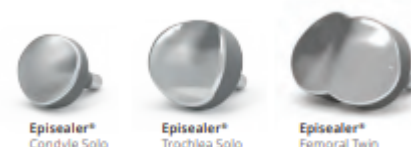
Episurf Medical's scalable µiFidelity® system has been developed for damage assessment, surgical pre-planning and cost-effective patient customisation of implants and associated surgical instruments. In a first step, the company's main focus has been on early stage arthritic changes in the knee joint.



Three different knee implants with a focus on early stages of arthritis

Episurf Medical currently has three types of patient-specific 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.



Patient-specific surgical instruments

Every product is delivered with our surgical drill guide Epiguide®. We also offer a surgical drill guide, Epiguide® MOS, that is designed for use in mosaicplasty surgery for treatment of cartilage and deep underlying bone defects in the knee 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 140 patents and patent applications worldwide, distributed over 20 patent families.

- » The first Episealer® surgery in a human was performed in December 2012. At the end of 2018, a total of 406 surgeries had been performed throughout Europe
- » 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

Highlights of 2018



- » Episurf Medical continued regulatory preparations and industrial partnership discussions in the US
- » Episurf Medical received market approval in Israel and signed distribution agreement for the Israeli market

- » Episurf Medical announced that the company is in the final stages of the development of an ankle implant
- » Episurf Medical signed financing agreement of up to SEK 70m which was approved at the AGM April 9th, 2018
- » Episurf Medical received another patent approval in the US related to Episurf Medical's 3D-based damage assessment tool
- » Episurf Medical presented long-term financial and operating targets



- » IDE application filed to the US FDA and FDA has indicated quick feedback
- » Strategic decision to enter the Indian market and regulatory preparations for India initiated
- » Strong commercial development in Germany
- » Promising clinical results, including 2-year follow-up data, accepted for presentations at several clinical congresses

- » 45 patients have now had their implant for more than 3 years and 15 patients more than 4 years
- » Appointment of Dr. Michael A Kelly as special study advisor for the US IDE study
- » Episurf Medical's knee products were approved for marketing and sale in Spain
- » Episurf Medical entered into a distribution agreement in Hong Kong and established subsidiary in the US
- » Katarina Flodström assumed the position Chief Regulatory Officer with responsibility for regulatory affairs, quality affairs and Intellectual property



- » Episurf Medical released new CE-marked joint visualisation tool based on AI
- » Episurf Medical has received initial feedback from the US FDA on the IDE application for the Episealer® knee Implant
- » Episurf Medical expanded into the Polish Market

- » Promising clinical results from use of Episealer® was accepted for presentation at the annual meeting of the Australian Knee Society in October
- » Clinical outcome for Episealer® was presented at the annual meeting of the European Orthopaedic Research Society (EORS) In Galway, Ireland In September
- » Patent approvals in Japan, US, Canada and Australia for Episurf Medical



- » Episurf Medical announced that the company had received approval from the US Food and Drug Administration (FDA) for its Investigational Device Exemption (IDE) application to initiate a clinical study on the Episealer® knee implant in the United States
- » Episurf Medical executed a directed share issue, raising SEK 13.2m. Through the directed share issue, the company gained a US shareholder among the largest shareholders and several existing shareholders increased their holdings

- » Niles Noblitt was appointed Senior Advisor to Episurf Medical
- » Episurf Medical announced the start of a new investigator-initiated clinical study conducted by Prof. H. Vandenuecker at the University hospital in Leuven, Belgium
- » Clinical outcome for Episealer® was presented at the annual meeting of the Danish Orthopaedic Society (DOS) in Copenhagen in October
- » New Chinese and US patent approvals for Episurf Medical
- » Episurf Medical was informed about the intention of its largest shareholder Serendipity Ixora AB to wind-up its operations and in conjunction thereto distribute its holdings of Episurf shares to its shareholders

Significant events after the end of the financial year

- » Episurf Medical announced the start of a comparative investigator-initiated clinical study performed at the Julius Wolff Institute, Charité University Hospital, Berlin

- » New Australian and Canadian patent approvals for Episurf Medical
- » Clinical results for Episealer® were presented at a German clinical congress in February
- » Episurf Medical reached milestone of 500 implants
- » Progress for Episurf medical in initiation of Episealer® Knee IDE study

Key ratios	2018	2017	2016	2015	2014
Number of surgeries performed	147	103	86	51	13
Number of new CE-marked products	1	--	1	2	1
Number of new patents	13	6	11	11	3



Dr. R. Kaelin, Dr. T. Rychen, C. Lüth and Prof. M.P. Arnold at an Episealer®-implantation

Statement from the CEO

Dear shareholder,

When entering 2018, we decided upon a new and focused long-term strategy for Episurf Medical. Also, we made sure that we had relevant and ambitious short-term targets for 2018.

When summarizing 2018, we can conclude that we took several important steps during the year. As a company, we have started to generate revenue, and we have demonstrated our ability to charge for our technology. We have established Episealer® as a treatment alternative in the treatment algorithm with several customers, although only at a fraction of our target market. We will continue to increase our volumes from current levels; however, additional clinical evidence is required for the Episealer® technology to establish itself on a significantly broader scale. That said, we have designed a relevant and focused strategy which will allow us to achieve our goal of establishing the Episealer® as a standardized treatment alternative within the orthopaedic industry.



Clinical evidence

One of our core strategies when entering 2018 was to ensure that a robust clinical pipeline was in place, and we can confidently say that this has been achieved.

Summary of clinical studies of the Episealer® technology

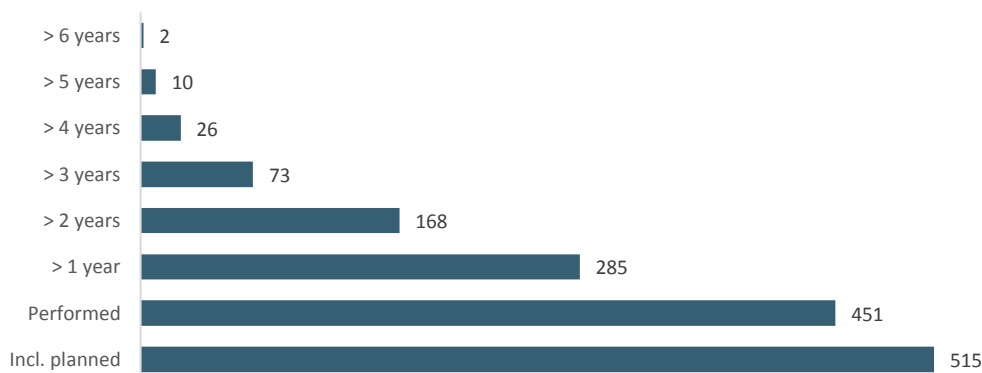
Description		Start-up phase	Patient recruitment phase	Fully recruited / data collection	Published
Pre-clinical study Episealer Knee	Focal knee resurfacing and effects of surgical precision on opposing cartilage. A pilot study on 12 sheep	✓	✓	✓	✓
Pre-clinical study Episealer Knee	Fixation of a double-coated titanium-hydroxyapatite focal knee resurfacing implant: a 12-month study in sheep	✓	✓	✓	✓
Pre-clinical study Episealer Knee	Treatment of full thickness focal cartilage lesions with a metallic resurfacing implant in a sheep animal model, 1-year evaluation	✓	✓	✓	✓
Pre-clinical study Episealer Knee	Cartilage Health in Knees Treated with Metal Resurfacing Implants or Untreated Focal Cartilage Lesions: A Preclinical Study in Sheep	✓	✓	✓	✓
Pre-clinical sheep study, Episealer® knee	Study on cartilage sealing with hydroxyapatite coated metal implants	✓	✓	✓	
Clinical trial, Episealer® Condyle solo	Swedish multicenter study, 10 patients, 24 months follow-up	✓	✓	✓	✓
Health economic study Episealer® knee	Comparative cost utility calculation showing economical scenario over 40 years	✓	✓	✓	
Clinical trial, Episealer® knee³	European multicenter clinical trial of 100 patients, 60 months follow-up	✓	✓	✓	
Episealer® knee	Swedish single center clinical trial of 30 patients, 60 months follow-up	✓	✓		
Clinical trial, Episealer® knee	X-Ray Fluoroscopic Analysis of knee joint kinematic in open and closed chain activities in patients with Episealer® Knee Implants	✓	✓		

Episealer® talus	European multicenter clinical trial of the ankle implant	✓	
EPIC-Knee study	Multicenter clinical trial (IDE) in the US and in Europe	✓	
Clinical trial, Episealer® knee	Investigator-initiated clinical study, following 30 Episealer® patients over 10 years	✓	✓

The above table summarises the most important clinical activities that are ongoing, and several hundred patients will be involved in clinical studies of the Episealer® device in the coming months and years. With the risk of sounding like a broken record, we must repeat our key message: We must have clinical evidence supporting the Episealer® technology. We are leaving our device in the human body, preferably for the rest of your life, in the joint that is exposed to the highest amount of stress, with the opposing area being natural cartilage. Naturally, customers and patients want clinical evidence supporting the procedure.

When writing this, we have just booked the 500th Episealer® surgery, and we now have several patients who have passed five years since surgery. Remembering the importance of the statement above, it is, of course, an achievement to have gotten this far with only a limited amount of clinical evidence available. It also says something about the potential we have once more data is available, and the long-term performance of the Episealer® is demonstrated in a larger number of patients over several years. Below, you will find a summary of our current patient population.

Number of surgeries and years since surgery



The two largest clinical studies that we are involved in are the European multicenter study and the EPIC Knee Study, which is the name of the US-study. In the European study, 11 orthopaedic surgeons from 7 countries have been following over 100 patients for several years. The study is fully recruited, and interim results were presented at several clinical congresses during 2018. These results presentations have generated a significant amount of interest, and we look forward to seeing these study results accepted for publication. The patients in the study demonstrated significant improvements across all the domains that are measured. The patients show significant improvements already after three months and the results show no signs of deterioration after two years.

The other study is the IDE¹ clinical trial in the United States. We are currently recruiting sites and working our way through the other administrative steps that are necessary before surgeries can take place. We received approval from the FDA in December 2018 to start the study, and it is fair to say that this approval was one of the most significant milestones ever for this company. The study will include 180 patients who will be followed for two years. The study will run in the US and in Europe, and we look forward to getting started with the surgeries shortly.

¹ Investigational Device Exemption

Global establishment

I believe we had a partial break-through in Germany during 2018. Our volumes in Germany were satisfactory as we reached almost 100% of our internal targets during the year, working with a limited group of surgeons. Our prospect lists are extensive and are in a dialogue with many potential customers. Germany is the market where we have reached the highest level of clinical acceptance, and the operational prerequisites are favourable to us. We are very optimistic about Germany in 2019. Our other home markets, namely the Nordic region, UK and Benelux are slightly behind Germany, but they all show great prospects for the future. We continue to focus the majority of our sales efforts towards these regions in 2019.

In addition to our home markets and the US market, we are looking at other markets which will constitute a mix of distribution markets and direct markets. In 2018, we secured regulatory access to the markets in Hong Kong, Spain and Poland, and we continued our establishment in Israel. We also communicated that we had initiated the regulatory and administrative work for the Indian market. The work has progressed well, and we look forward to updating investors on the next step in this exciting market.

Secure reimbursement and production enabling attractive margins

Regarding reimbursement, most of our work is related to the activities regarding clinical evidence. These topics are closely related, and we need additional clinical evidence before we can make new break-throughs on reimbursement. We were able to charge attractive prices in 2018, but ideally, we could affirm our position further with stronger reimbursement.

As previously communicated, our investments in the improvements of gross margins are focused towards the software related parts of the production chain. Through the critical steps we took with our proprietary developed damage marking tool, Epioscopy® in 2018, we laid out the foundation for faster and smoother operational processes, which also will decrease costs.

Technological and clinical relevance through a high degree of innovation

Our commitment to technology and clinical excellence remains. We are continually striving towards being at the top of our game. We know that our Episealer® implant technology represents a ground-breaking treatment alternative for our target indication, and we can expand our offering based on our technology platform.

Our CE-approval of Epioscopy® in Q3 2018 was a significant milestone for us. Epioscopy®, which is a tool for surgeons, patients and other healthcare professionals, is a web-based application based on artificial intelligence (AI), providing an overview of a knee joint's clinical condition. We see a broad range of application areas for Epioscopy®, but it is important to remember that it is not only a new product, it also improves the current process flow for the Episealer® product line. Regarding the other prioritized project, our ankle implant for osteochondral lesions of the talus bone in the ankle joint, we are still awaiting CE-approval. We have to admit that we had hoped to obtain this already in 2018. However, our dialogue with the notified body is very productive, and we see good progress. We are very excited about this product as we know that it is in high demand and we have a strong surgeon network within the ankle segment.

Concluding remarks

I ended my CEO statement last year by saying that I hoped that we would become a much stronger company in 2018. I can confidently say that this is the case. We do not have the brand name or reputation from one of the large established orthopaedic companies, but the Episealer® is becoming increasingly known in our target markets. With clinical data showing excellent results presented at a large number of clinical congresses during 2018, soon 500 surgeries performed, and a growing user base, we are establishing ourselves day by day. Our growth will continue, and we are confident that our strategy is the correct one for this to happen. The Episealer® technology is a technology for the future.

Stockholm, March 2019

Pål Ryfors, CEO

Statement from the Chairman of the Board

Dear Shareholders,

Efficiency in the execution of our strategy have been the focus for our company in 2018 and this will continue in 2019. Because of the heavy investment it takes to be a successful high technology medical device company, we have no choice but to make sure every financial decision produces progress.

In 2018, we entered a very important stage of our development which will require even more focus on efficiency and greater progress on the world stage of Orthopaedics. What we learned in 2018 is that the worldwide medical device market is moving more toward advanced technology. We are uniquely positioned as a company that combines technology in the pre-surgical planning phase with our exclusive cartilage damage report process with tailor-made bone surface restoration implant.

There is a distinct division of the various medical device start-ups around the world. First, those who are simply making an implant better, like “easier to use” and “cost less”. Then there are products from Episurf and others such as robotics, advanced materials and electronics that are truly making a difference for the patient.

We are seeing start-up companies who offers standardized products beginning to consolidate. And we are seeing higher technology companies, such as our company, cause clinicians, providers and payors start preparing themselves for the future. This will include a significant focus on clinical studies, training and education, which are key attributes of Episurf.

Our Board of Directors all have an area of expertise that will continue providing guidance, and we have new shareholders, I would like to mention Niles Noblitt, who see the future and are providing market confidence in our mission.

2019 will take more work, take more focus, create more clinical advocates and be a major flection point in our business. Please join me in supporting Pal and his team, as they keep moving forward.

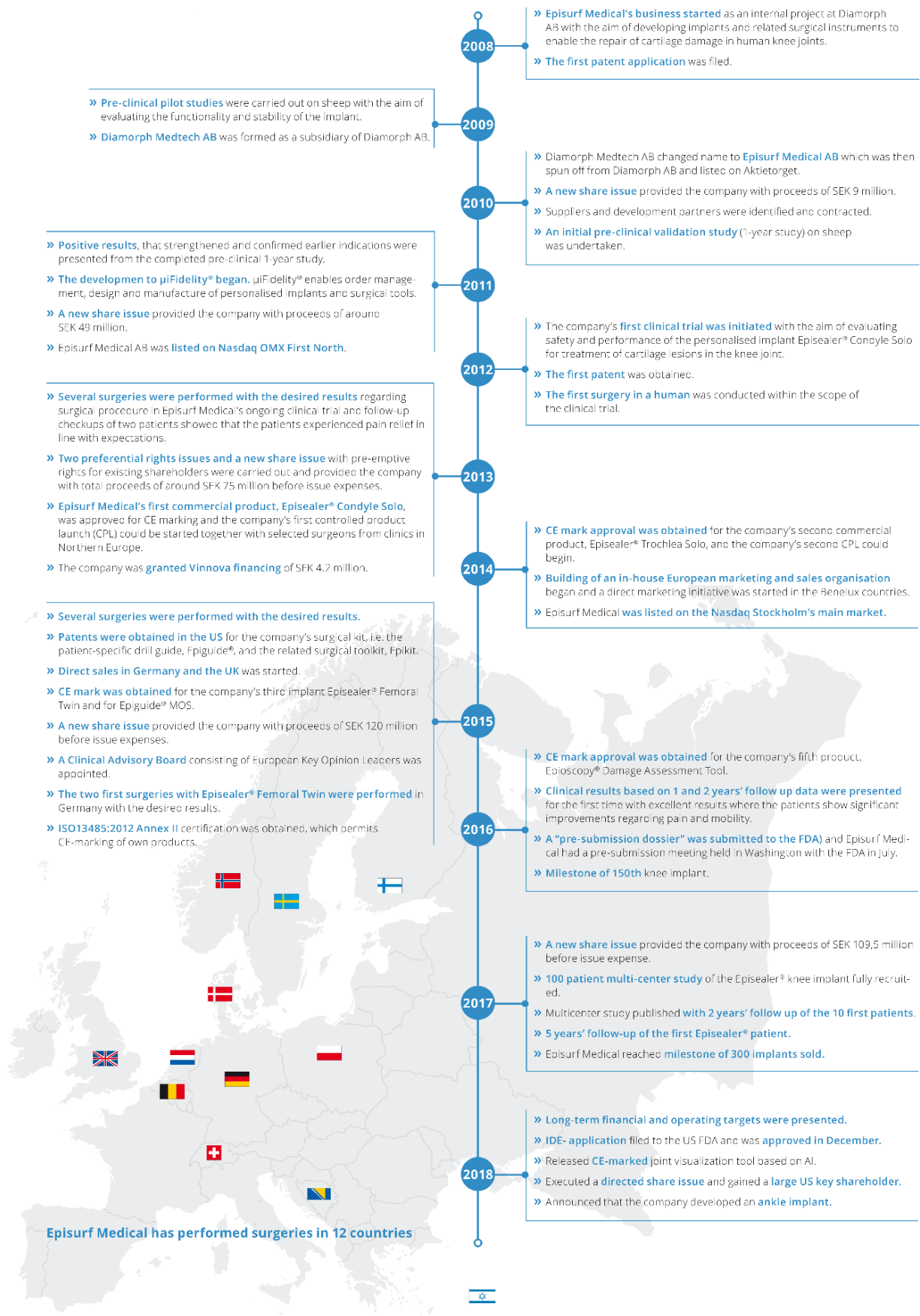
New Jersey, March 2019

Dennis Stripe
Chairman of the Board



***Dennis Stripe, Chairman of the Board,
together with Board member Leif Ryd***

History



Interview with patient and his surgeon

Markus Arnold is professor of orthopaedics in Basel, Switzerland and specialised in knee disorders. Prof. Arnold started to use the Episealer® knee implant almost five years ago and we asked him about his experience as Episealer® user and if we could get in contact with one of his patients and hear about his experience as patient.

Prof. Arnold, you performed your first Episealer® surgery in 2015, what convinced you to start using Episealer®?

When I first heard about the new, personalised mini-implants I was convinced that this was a good idea. Before Episealer® I never implanted mini-implants because I did not like the concept and the reported results. I felt that there was a treatment gap between biologic solutions in younger patients for localised cartilage lesions and the prostheses for more generalised OA in older patients. Episealer® filled that gap.

For which patients do you use Episealer®?

The ideal group of patients for me is the following:

- Patients with failed previous biologic treatment
- Localised osteochondral lesions in patients >55 years or younger patients with a borderline indication for biologic treatment (no kissing lesion, minor lesions on the patella, more important lesion in the trochlea for instance)
- Patients who need a relatively fast recovery period and cannot afford to wait 12 months as is necessary after a cartilage repair

How did you use to treat patients with focal chondral and osteochondral lesions in the past?

We use the full spectrum of joint preserving therapy modalities, from osteotomies, to osteochondral repair, but yes, those patients were always a challenge.

What made you suggest an Episealer® for the patient?

My first Episealer® patient was a special one, of course: 70 years old, the knee in a generally healthy state, but an old OCD-lesion became suddenly unstable and left a considerable lesion in the medial femoral condyle. Instead of a partial knee replacement, which would have been one classical solution, we chose the localised resurfacing method Episealer®.

What benefits do you find with Episealer®?

We know that the implant will fit the patient's lesion in every case because it is patient and lesion-specifically designed, the possibility to interact with the implant designing team and finally the reliably, good results.



Prof. Markus Arnold speaking at the 2018 ESSKA Congress in Glasgow

Interview with one of Prof. Arnold's patients



One of prof. Arnolds patients, Jörg from Oberdorf in Switzerland, that received an Episealer® in March 2018.

When and how did your knee problem start?

The pain in the left knee began due to heavy load after an ankle fracture in the right leg (ankle surgery in Nov 2017). Due to the six weeks of rehabilitation after the ankle surgery, the left knee was heavily loaded and the pain in the knee occurred. After seeking Prof. Arnold for an examination, he suggested implantation of an Episealer® to me.

How was your life before the surgery? Did the knee pain impact your life?

Going up and down the stairs was a torture to me. Longer walks with our dogs became less and less possible. My quality of life was clearly limited, like walking in the nature. I looked with very great interest forward to an improvement.

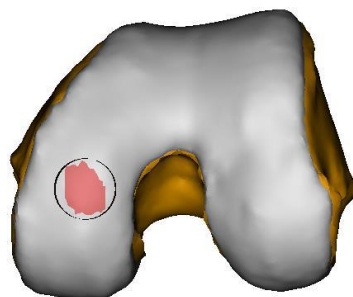
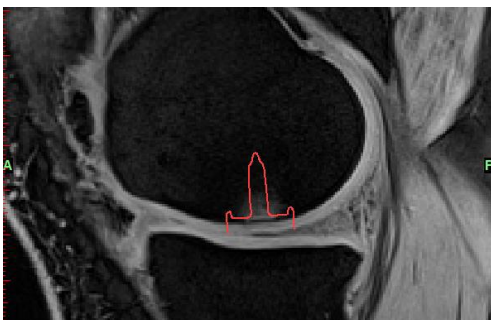
Did you have any previous knee treatments prior to the Episealer® surgery?

No, Prof. Arnold highly recommended this procedure to me.

"Today, after nearly a year, I can do practically everything again."

Where any alternative treatments discussed as an alternative to the Episealer®?

We talked about a partial prosthesis of the knee, but we found it would have implied a too extensive intervention. Some other alternatives were discussed but they would have implied long rehabilitation and walking for weeks on crutches was not an alternative for me.



Focal lesion on the medial condyle of Jörg's left knee.

Your rehabilitation after surgery - how soon could you go back to work and live normally?

After the four-days' hospital stay, I began my physiotherapy according to the hospital's instructions. At the beginning I treated the swollen knee with lymphatic drainage twice a week with great success (altogether about 15 treatments). Already after four weeks I exercised the knee for a long time on the home trainer. Six weeks after the operation I cycled on the streets with the e-bike. I could adjust the settings with more or less power to support me on the slopes and be on the road for two to three hours.

How would you describe your life today?

Today, after nearly a year, I can do practically everything again. When loading the knee, be it on hikes or on the e-bike, I feel no pain. After efforts, in the resting phase, I may still feel a pressure in the knee, depending on how heavy I have loaded the knee. It is never swollen, but the outside of the knee feels numb. Because of the scar, so far, I cannot kneel with my left knee.

All in all, I am very satisfied with the result of this surgery and I can really recommend this method.



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-arthritic 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 were required. New design criteria were 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 μ Fidelity®. 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. During 2015 CE mark was further received for the surgical guides Epiguide® MOS. 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. The company’s fifth product, Epioscopy® Damage Assessment Tool received its CE-mark approval 2016 and an updated version received its CE-mark approval in September 2018.

Episurf Medical's technology

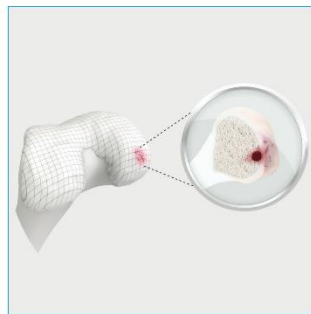
From MRI to customised implant and surgical tools

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.



- 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 Bring people back to living life



BUSINESS IDEA Provide orthopaedic surgeons with qualitative and clinically superior patient specific treatment alternatives



GOAL Establish our patient specific technology in the treatment algorithm for focal cartilage and bone lesions and become a highly profitable and innovative company in the orthopaedic industry
Long-term market share goal: Episurf Medical estimates that its addressable market for Episealer®

knee implants in Europe, Asia and the US amounts to 150,000 patients annually, and its goal is to achieve a 10% penetration of this market, for annual sales of 15,000 units. Long-term profitability goal: Episurf Medical targets a long-term operating margin of 40% driven by improvements in gross margins by significant increases in the automation of the company's process for damage assessment and by large scale economies expected as manufacturing steps are brought in-house and the supply chain is optimised.

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

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. Additional case reports and patient follow-ups from patients who have exceeded 3 – 5 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 European 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 is starting a clinical study for the purpose of receiving FDA approval for marketing of the Episealer® technology. The study will run as a combined US and European multicenter study.
- » As previously communicated, execution of our US strategy might best be pursued together with a partner. Episurf Medical has engaged in early collaborative discussions.



Secure production and reimbursement enabling high margins

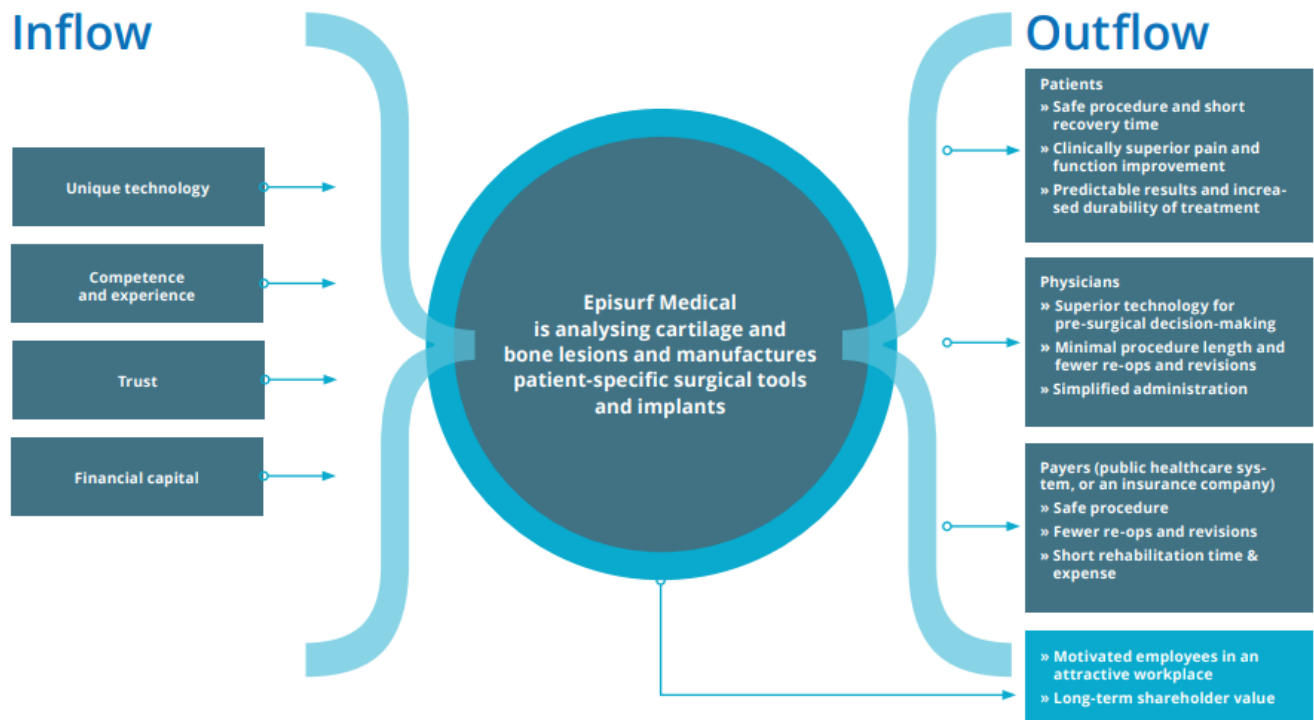
Securing reimbursement in relevant markets is a key success factor for the company and Episurf Medical will continue its work in selected markets. The company will also continue its work towards improving gross margin. In the near term, investments are primarily directed towards software development 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. 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.
- » The company continues to develop its imaging technology and following the launch of the ankle implant, this product has the highest priority in the company's product development pipeline.

Business model



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, Parkclinic Manhagen.



Professor Mats Brittberg 
Sweden

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



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.

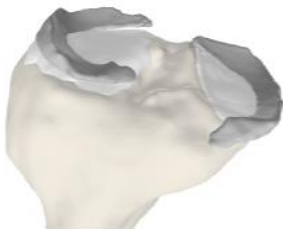
Epioscopy®

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, 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 which are otherwise generally surveyed during an arthroscopy.



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

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, correlating on-screen with the patient's MR images.



"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

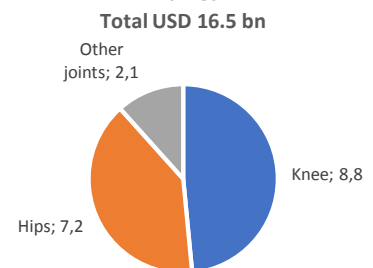
Episurf Medical's first patient-specific product portfolio, the knee portfolio, consists of the existing products Episealer® Condyle Solo and Episealer® Trochlea Solo, Episealer® Femoral Twin, Epiguide® MOS and Epioscopy®. The first product portfolio is focused on treatment of cartilage damage in knee joints, and addresses a potential market worth many billions of US dollars.

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 35–65 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.

An estimated 3.6 million Americans (20 % of patients with symptomatic OA) are found in a large so-called "treatment gap".² These are patients at an active age with early-stage unilateral osteoarthritis.³ They are too young and active for knee replacement surgery, but are too old and have too extensive damage for successful treatment with traditional biologic methods for cartilage defects. Studies in the US show that the average age of those suffering from osteoarthritis fell from 72 to 56 years between 1990 and 2010, a full 16 years over the course of two decades.⁴

Figure 1. The global joint reconstruction market



Source: The Orthopaedic Industry Annual Report 2017

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. 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.

² Li, C., et al., Orthopedic surgeons feel that there is a treatment gap in management of early OA: international survey. *Knee Surgery, Sports Traumatology, Arthroscopy*, 2014. 22(2): p. 363-378

³ London, N.J., L.E. Miller, and J.E. Block, Clinical and economic consequences of the treatment gap in knee osteoarthritis management. *Medical Hypotheses*, 2011. 76: p. 887-892

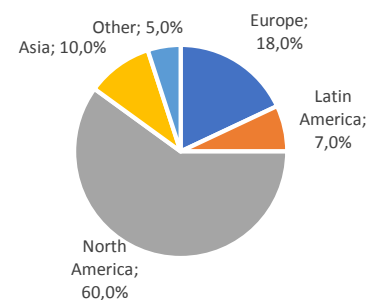
⁴ <http://publichealthintelligence.org/content/life-expectancy-progress-1990-2013>

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.⁵ According to studies reported, 5 percent of the US population over the age of 50 is living with a prosthetic knee joint.⁶

Over the past decade, the number of knee replacement procedures on patients under the age of 65 years has increased dramatically.⁷ The ten largest markets for knee replacement surgery are the US, France, Germany, Italy, Spain, the UK, Japan, Brazil, China and India. Some 1.5 million surgeries are performed every year in these markets.⁸ 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.⁹

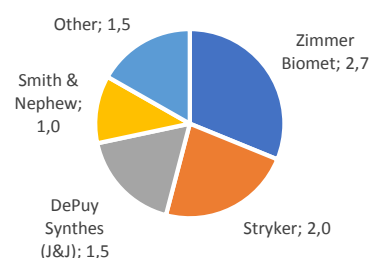
The prostheses used in knee replacement surgery today have an expected longevity of 15–20 years and in light of this, most orthopaedic surgeons recommend that patients wait until they have reached the age of 65 before undergoing this surgery. Furthermore, at present a small share is treated with partial 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.¹⁰ 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 2006.¹¹

Figure 2. The global market for knee arthroscopies



Source: Transparency Market Research 2016

Figure 3. Market share in the global knee market
Total USD 8.8 bn



Source: Transparency Market Research 2016

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.¹² In the US alone, some 3.7 million knee arthroscopies are performed every year.¹³ The corresponding figure for Europe is 1.1 million per year.¹⁴ Research shows that of these knee arthroscopies, between 7–13 percent show traumatic or degenerative cartilage defects of ICRS grade III and IV¹⁵, implying that the cartilage defect extends

⁵ 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

⁶ <https://www.newswise.com/articles/knee-osteoarthritis-to-increase-in-younger-age-groups-in-next-ten-years>

⁷ <https://www.newswise.com/articles/knee-osteoarthritis-to-increase-in-younger-age-groups-in-next-ten-years>

⁸ <http://newsroom.aaos.org/media-resources/Press-releases/knee-replacements-linked-to-obesity.htm>

⁹ Global Data, Orthopedics Devices Market, Global

¹⁰ Global Data, Orthopedics Devices Market, Global

¹¹ Global Data, Orthopedics Devices Market, Global

¹² Transparency Market Research 2016, Arthroscopy Procedures and Products Market – Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2015-2023

¹³ Transparency Market Research 2016, Arthroscopy Procedures and Products Market – Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2015-2023

¹⁴ Transparency Market Research 2016, Arthroscopy Procedures and Products Market – Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2015-2023

¹⁵ 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

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.

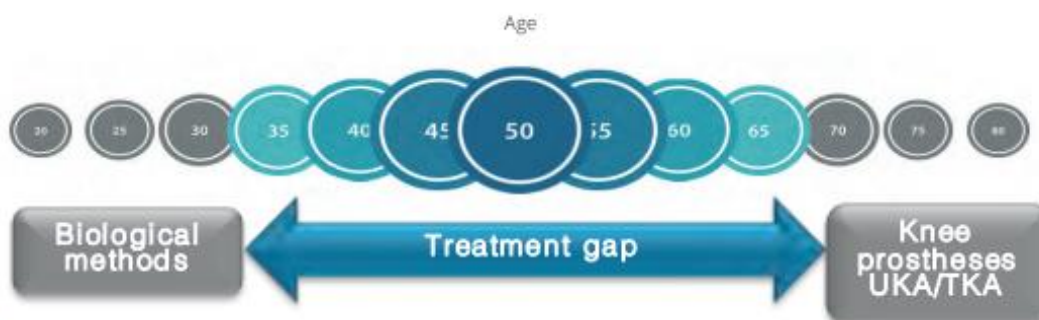
Existing treatment gap

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 knee 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).

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).¹⁶ Episurf Medical addresses this treatment gap with its unique damage marking report and patient-specific Episealer® product range.

Existing treatment gap



al., *Articular Cartilage Lesions in 993 Consecutive Knee Arthroscopies*. The American Journal of Sports Medicine, 2004. **32**(1): p. 211-215

¹⁶ 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

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.¹⁷ The World Health Organization (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.¹⁸ The corresponding figure for 2015 is estimated at 2.3 billion overweight and more than 700 million obese.¹⁹

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.

Reimbursement

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 could be the government in the public healthcare system, or an insurance company if the patient has private health insurance.

The patient is not responsible for the clinical decision about which treatment or product to use. This decision is made by the doctor within the existing regulatory framework. These regulatory frameworks vary between markets but usually include a mix of both clinical and economic factors.

Reimbursement is a prioritized area for Episurf Medical and the Company is continuously working with this within the prioritized markets.

¹⁷ <http://www.vetenskaphalsa.se/okad-risk-for-artros-aven-vid-latt-overvikt/>

¹⁸ http://www.who.int/gho/publications/world_health_statistics/2013/en/

¹⁹ http://www.who.int/gho/publications/world_health_statistics/2013/en/

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 30–70 years with knee joint 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:

- 1) Episealer® implants
- 2) Episealer® toolkits
- 3) Damage marking report (Epioscopy®)

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 ANKLE

Our latest implant – 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 will launch a solution for treatment of bone and cartilage defects in the talus bone of the ankle joint.

The ankle joint

The ankle joint is the 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. Bone and cartilage 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.

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 patient-specific osteotomy guide (saw guide), developed by Episurf Medical and designed and manufactured with the same MRI and 3D technology as the Episealer® drill guide, Epiguide®, it will be easy 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 will be 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.

Statement by Professor Leif Ryd

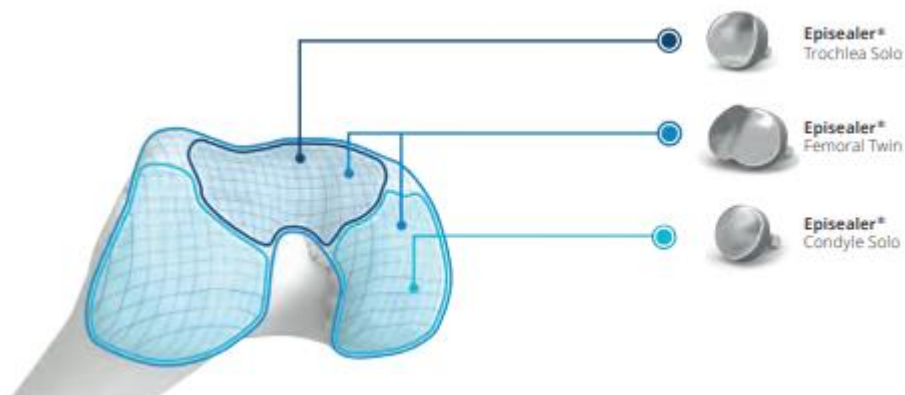
"I very much look forward to the launch of Episealer® Talus, especially as we have received many requests from surgeons asking if we could develop an implant system for this application. The total market for a talus implant might be smaller than the market for knee implants but as we understand it from all surgeons who have contacted us, we really meet a demand from the market as the alternative treatments are very limited. Also, the Episealer® Talus project confirms that the Episealer® technology is applicable outside the knee joint."

PRODUCTS FOR THE KNEE

Episealer® individualised implants

Episealer® knee implants

Episurf Medical's Episealer® 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® 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. 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 a 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.²⁰ In one of these publications'

²⁰ 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

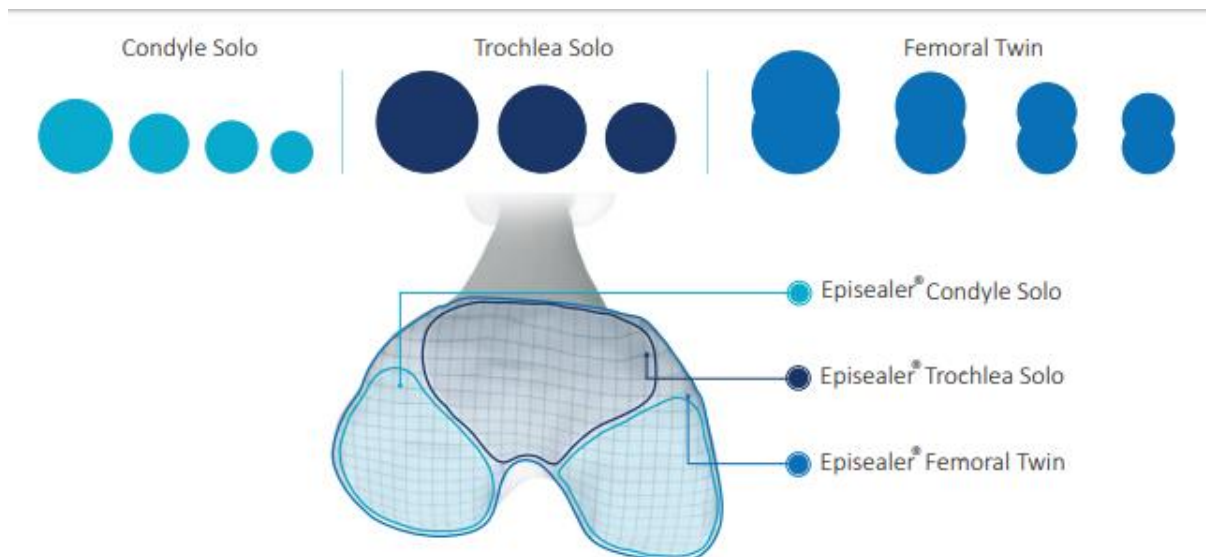
adherence between cartilage and the HA-coated was reported, and a concept of sealing of the interface between cartilage-bone and implant is discussed. This effect can prevent joint fluid from penetrating the metal-bone interface and thus minimise risks of osteolysis and cyst formation. The sealing effect 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 somewhere else in the knee.

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. 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 knee anatomy. This will not ensure a perfect fit which may compromise the clinical outcome of the surgery. Further, more lesions/implant positions in the knee can be addressed with the truly patient-specific Episealer®, providing unlimited choices of implant surface curvature.

Market launch	Product line	Age range		Indications
		20-40	35-65	
CE mark approval	Episealer® Condyle Solo		●	Chondral and osteochondral defects of ICRS grade III-IV
CE mark approval	Episealer® Trochlea Solo		●	Chondral and osteochondral defects of ICRS grade III-IV
CE mark approval	Episealer® Femoral Twin		●	Chondral and osteochondral defects of ICRS grade III-IV



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 an Epioscopy® damage marking report. This report is generated through the use of magnetic resonance imaging and creation of a virtual 3D model which is a replica 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 scan of the patient's knee is performed, anonymized and sent digitally to Episurf Medical through the order management system µiFidelity®. The quality of the MR images is checked. Based on the MRI data, the geometry of the knee as well as the extent of the cartilage and bone damage are assessed and visualised together with an Episurf Medical radiologist

A virtual 3D model of the affected knee 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.

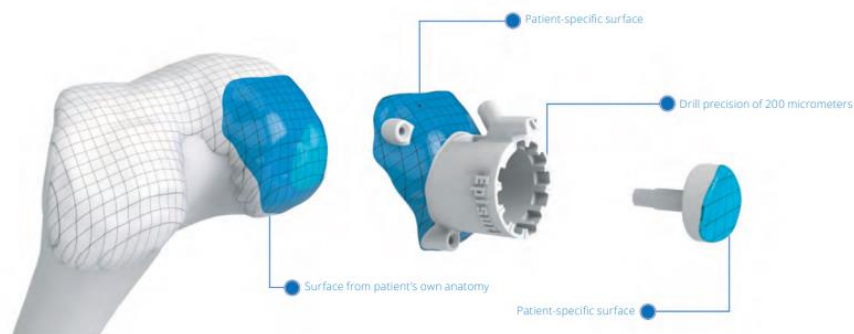


Episealer® Toolkit

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.

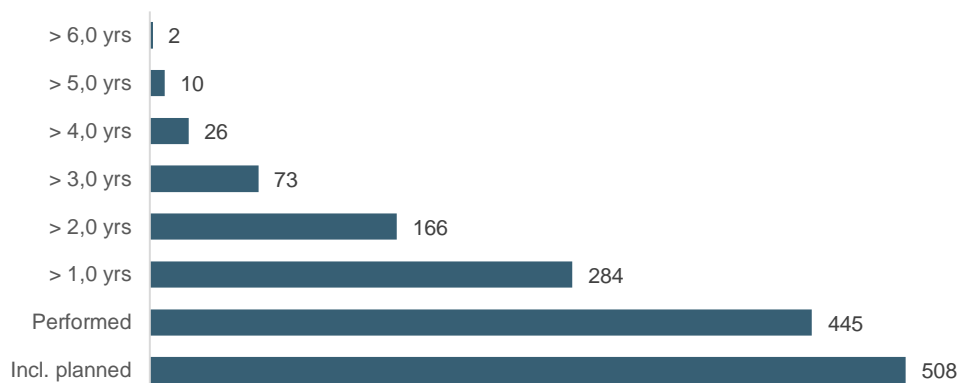
The single use toolkits for the implants consist of the following parts:

- 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) 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.



Clinical evidence

Years since surgery by reporting date



Of all initiatives we take, our investments in clinical evidence are among the most important investment. Surgery should not be a guesswork, that's what we said from the first day when we started to develop the Episealer®. That's why every Episealer® starts with a damage marking report where we show the condition of the patient's knee with focus on our area of expertise, the cartilage and bone.

We must be sure that every time we deliver an Episealer, the implant will perfectly fit the knee and the defect. Because it should not be a guesswork.

We have also, from the very beginning, invested in research. As a part of the development of the Episealer®, four pre-clinical studies were performed in order to make sure that our concept would work and to assure that we were ready for clinical use.

The first patient to receive an Episealer® had his surgery in December 2012. He was one of ten patients who were included in our first clinical study from which 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. was published in the KSSTA in November 2017. The study concludes good implant safety and patient satisfaction and the knee function as well as pain is significantly improved.

"Getting evidence takes time – it takes five years to get five years' results."

As it takes time to collect results, we are grateful that some of the very first users of Episealer® agreed to follow up their patients and prepare for a publication of their results. Clinical data from this follow-up has during 2018 been presented as abstracts at eight national and international orthopaedic congresses. This has resulted in a study where 100 patients are followed over five years. The abstracts have been concluded with the words "Rapid pain relief" and "Excellent early clinical results".

The study group has stated that they plan to submit the first manuscript with interim results for scientific publication in the second quarter 2019.

In January 2019, the investigator-initiated study "X-Ray Fluoroscopic Analysis of knee joint kinematics in open and closed chain activities in patients with Episealer® Knee Implants" was initiated at Charité University Hospital, Berlin. The study will follow up patients that have undergone an Episealer® procedure and assess the joint mobility of the treated knee and compare with healthy, non-treated knees as well as benchmark against knees that have undergone total knee arthroplasty (total knee replacement). This study is highly interesting and we

expect that this study will prove the excellent knee function at Episealer®-patients which previously mentioned studies indicate and many patients themselves told us about.

In addition to the above, an investigator-initiated study is being performed by Prof. H. Vandenuecker at the University Hospital in Leuven, Belgium. The study will follow 30 Episealer® patients over ten years and the goal is to evaluate the efficacy, safety and performance of the Episealer® device in a larger sample size and in the long term.



Our most important new initiative 2018 was our IDE study. This randomised controlled study will compare the clinical outcome of the use of the Episealer® knee implant with the currently most common surgical procedure, microfracturing. The study will be performed at around 16 sites in Europe and USA and 180 total subjects will be randomised at a 2:1 ratio to either the Episealer® group (n=120) or the control group (n=60). The patients will be followed over 2 years. The study objectives are to evaluate the safety and clinical effectiveness of the Episealer® Knee System and assess improvements in subject reported pain and quality of life. The outcome will form the basis for Episurf's future submission to the US FDA (Food and Drug Administration) for market approval through the so-called PMA (Premarket Approval) route. The study will in addition to verifying the clinical outcome, also evaluate the treatment alternative from a health economic perspective.

"The IDE study is one of the most important strategic initiatives in the company's history and in addition to be a pathway to FDA approval, this study will also support our global expansion initiatives." Katarina Flodström



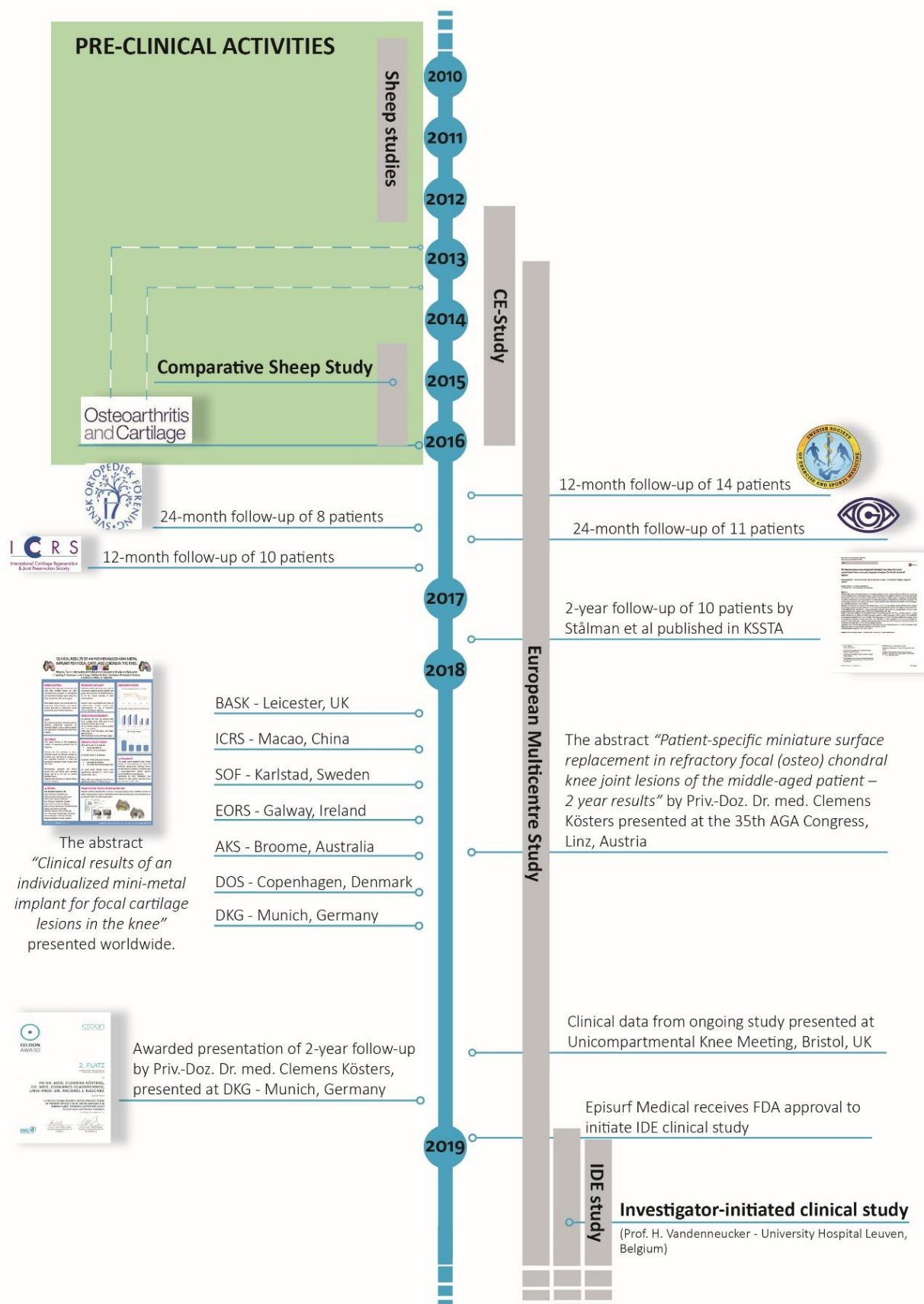
Our users, the orthopaedic specialists, take decisions based on evidence. Their daily work must never be a guess work. They make sure that the treatment they use for their patient is the best treatment available.

Today, Episealer® is often used as the second alternative after trying biological alternatives such as microfracture or ACI. After such primary surgery, it is not uncommon that the initial focal lesion has turned in to a more severe defect, sometimes not treatable with an Episealer®.

Our users who have used the Episealer® for some time now tend to use Episealer® as a primary alternative for patients above 40-45. By being able to prove the clinical outcome shown in ongoing studies and later on being able to show the difference in

"It takes time to collect data – to be precise; it takes five years to collect five-years' data. With 30% of our 400 treated patients followed-up within clinical studies and 10 of them having had the implant for five years or more, we are now at a stage where our users can start publishing the results of their follow-up. We look forward to seeing 2019 being the year when we will be able to prove to the market that Episealer® is an excellent treatment alternative - treating the defects, restoring the joint and bringing the patients back to active life!" Leif Ryd

clinical outcome between Episealer® and microfracture, we are convinced that the number of surgeons who trust to use Episealer® as a primary treatment will significantly increase. That would also imply that we get a chance to treat many more defect knees in time, before it's too late.



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.

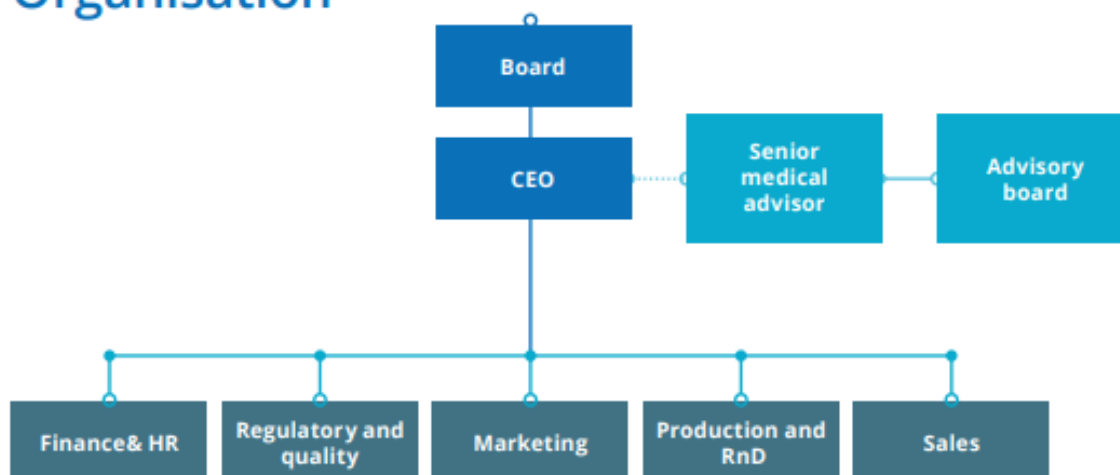
THE AVERAGE NUMBER OF EMPLOYEES in the Group during 2018 was 25, of whom 12 women and 13 men. The number of employees in the Group at the end of 2018 was 24, which is a decrease of 2 employees compared to year end 2017.

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.

In pace with Episurf Medical's development, the organisation is being adapted and during the year changes were made in the company's management team. In June 2018, Ladan Amiri left the company and thus the management team, she was replaced by Katarina Flodström, Head of Regulatory Affairs, Quality and Patents.

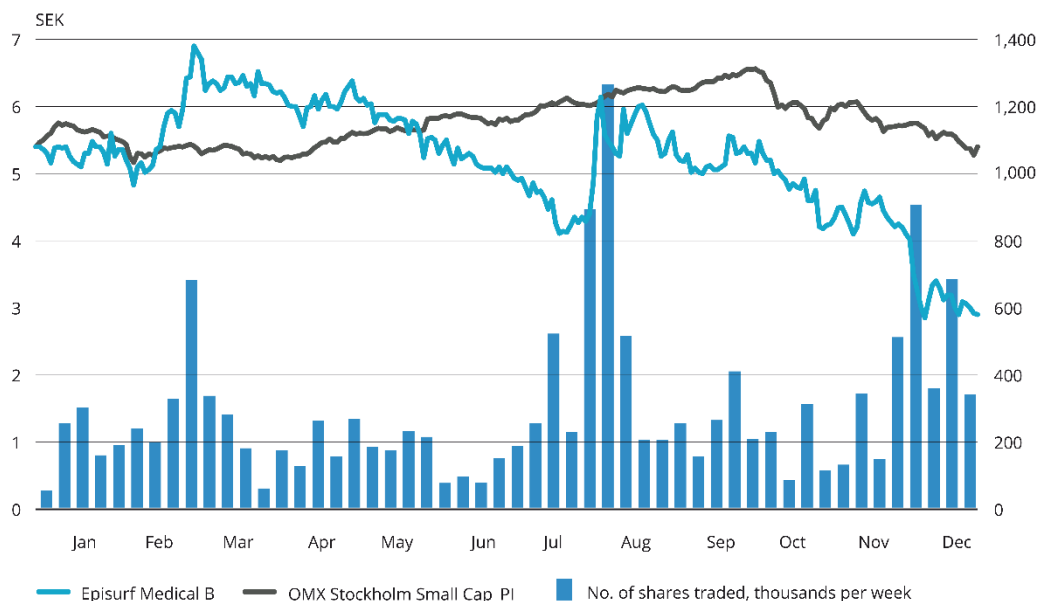
Organisation



Share capital and ownership structure

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

Share price performance during 2018



Source: SIX

General information

The company's shares are issued in two classes. As of the date of this annual report, the company's registered share capital amounts to SEK 9,497,382.90 distributed among 5,221,662 A shares (ISIN: SE0003523869) and 26,409,507 B shares (ISIN: SE0003491562), corresponding to a total of 31,631,169 shares. The quota value of each share is SEK 0.3. According to Episurf Medical's current articles of association 31 December 2018, the share capital may not be less than SEK 4,500,000 and not more than SEK 18,000,000 represented by no less than 15,000,000 and no more than 60,000,000 shares.

The company has during December 2018 completed a new directed share issue, 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 in Episurf Medical AB at December 31 2018*

	No. of A-shares	No. of B-shares	Share capital in %	Voting rights, %
Serendipity Ixora AB	4,601,519	–	14.6	32.8
UBS Switzerland AG; W8IMY	112,066	2,439,616	8.1	6.6
Försäkringsaktiebolaget, Avanza Pension	–	1,526,515	4.8	3.6
Skandinaviska Enskilda Banken, W8IMY	–	1,376,356	4.4	3.3
AMF Aktiefond småbolag	–	1,164,448	3.7	2.8
Gile Medicinkonsult AB	279,945	142,954	1.3	2.3
LMK Forward AB	–	938,000	3.0	2.2
Nordnet Pensionsförsäkring AB	–	755,903	2.4	1.8
Pål Ryfors	–	666,393	2.1	1.6
BNY Mellon SA/NV (Former BNY), W8IMY	–	630,194	2.0	1.5
Total, 10 largest shareholders	4,993,530	9,640,379	46.3	58.5
Summary, other	228,132	16,769,128	53.7	41.5
Total	5,221,662	26,409,507	100.0	100.0

*As stated in the information above, the shares issued in the directed share issue, including the shares issued to Mr Niles Noblitt, was registered in the beginning of January, hence not included in the table above. Pål Ryfors has lent out 350,000 shares to the European Select Growth Opportunities Fund and owns a total of 1,016,393 shares. No interest expires.

Ticker symbol:	EPIS B
ISIN code AK A:	SE0003523869
ISIN code AK B:	SE0003491562
Order book ID:	78,419
No. Of shares outstanding:	31,631,169
Quota value:	0,3
Round lot:	1 share
Share capital:	9,497,382.90

Share issues and share conversions

At the request of shareholders in Episurf Medical, class A shares have been converted to class B shares on several occasions during the year in accordance with the Articles of Association.

The company has during December 2018 completed a new directed share issue to a number of selected investors, including Niles Noblitt, one of the founders of Biomet, and the current shareholder Rhenman Healthcare Equity L/S. The shares of series B were issued at the subscription price of SEK 4.00 per share. In total, 3,290,210 shares of series B and all 2,252,210 warrants were subscribed for. The share issue was consequently not fully subscribed. In total, SEK 13.2 m before transaction costs was contributed to Episurf. Through the share issue, Episurfs share capital was increased by SEK 1.0m. The total number of shares thus increased by 3,290,210 B-shares and the same number of votes. The directed share issue was registered at the Swedish Companies Registration Office on January 9, 2019.

To assure financing of continued operations, a financing agreement with European Select Growth Opportunities Fund (“ESGOF”) was entered into in February and decided on the Annual General Meeting in April 2018. The agreement provides the company with access to SEK 70m over a 36month period in form of convertible debt securities divided into a number of tranches.

In connection with each tranche of convertibles, warrants are also issued to ESGOF.

When convertibles and warrants are issued to ESGOF, warrants are also issued free of charge to existing shareholders.

As of December 31, 2018, the Company has issued 140 convertibles to ESGOF, which can be converted into B-shares in the Company, and 2 279 002 warrants to ESGOF and existing shareholders, which entitle to subscribe for B-shares in the Company. The conversion price that determines the number of shares that can be converted to depends on, among other things, the time of conversion and the Company’s share price. As of December 31, 2018, ESGOF converted 82 of these convertibles to 1,081,674 B-shares.

Share price performance and trading

Episurf Medical's share price at year-end was SEK 2.9 (5.4), which is equal to a market capitalisation, calculated on the total number of class A and B shares, of SEK 91.7 million (165.0). During the financial year, the share price changed by -46,3 per cent (-64.0). The highest price paid during the year was SEK 7.0 (18.3) and the lowest was SEK 2.75 (5.25). During the year, 15,136,610 class B shares were traded on Nasdaq Stockholm (14,011,044) for a total value of SEK 76.3 million (108.0).

Ownership structure

The number of shareholders at year-end was 3,502 (3,070). The ten largest shareholders in Episurf Medical in terms of voting power held shares corresponding to 46.3 per cent (48.0) of the share capital and 58.5 per cent (61.7) of the votes. The largest shareholder, Serendipity Ixora AB, held shares corresponding to 14.6 per cent (15.3) of the share capital and 32.8 per cent (32.3) of the votes.

Ownership structure by size of holding at 31 December 2018

Holding	No. Of shareholders	Class A shares	Class B shares	% of capital	% of votes	Market value (SEK 000s)
1-500	1,524	2,276	241,676	0.77%	0.59%	701
501-1,000	531	4,062	436,368	1.39%	1.07%	1,265
1,001-5,000	909	15,400	2,327,106	7.41%	5.64%	6,749
5,001-10,000	263	24,860	2,004,817	6.42%	4.94%	5,814
10,001-15,000	75	--	947,880	3.00%	2.25%	2,749
15,001-20,000	53	15,200	965,427	3.10%	2.40%	2,800
20,001 -	147	5,159,864	19,486,233	77.92%	83.10%	56,510
Total	3,502	5,221,662	26 409 507	100,00%	100,00%	76,558

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	986,898	34,921,379	10,484,281

*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 2018 to 31 December 2018.

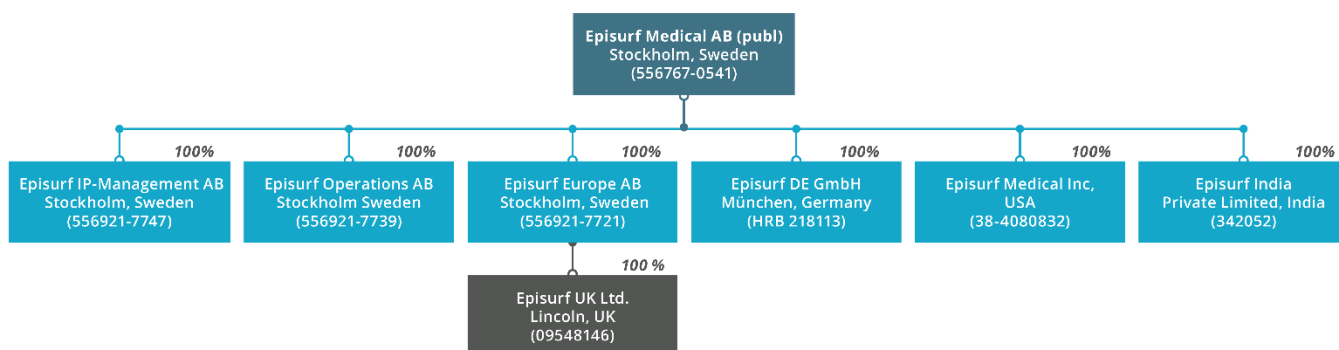
Group structure

The structure of the Group is described in the figure, 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, founded in 2009 (company formation in 2008), 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 35–65 years with focal cartilage and bone defects of the knee 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 patient-specific product portfolio, focused on treatment of cartilage damage in knee joints, consists of the five CE-marked products; Episealer® Condyle Solo, Episealer® Trochlea Solo, Episealer® Femoral Twin, Epiguide® MOS and Epioscopy® Damage Assessment Tool.

Research and development

Costs for development have during the year been capitalised with SEK 4.3m (3.7). 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 have been granted European market approval in the form of a CE mark, they are in a first step being introduced to selected leading clinics and surgeons primarily in Northern and Central Europe, in which treated patients are followed up clinically. This so-called prelaunch phase takes around one year. 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. Aside from the Nordic and Benelux countries, the company's primary markets in 2019 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 continued regulatory preparations and industrial partnership discussions in the US
- » Episurf Medical received market approval in Israel and signed distribution agreement for the Israeli market
- » Episurf Medical announced that the company is in the final stages of the development of an ankle implant
- » Episurf Medical signed financing agreement of up to SEK 70m which was approved at the AGM April 9th, 2018
- » Episurf Medical received another patent approval in the US related to Episurf Medical's 3D-based damage assessment tool
- » Episurf Medical presented long-term financial and operating targets
- » IDE application filed to the US FDA and FDA has indicated quick feedback » Strategic decision to enter the Indian market and regulatory preparations for India initiated
- » Strong commercial development in Germany
- » Promising clinical results, including 2-year follow-up data, accepted for presentations at several clinical congresses
- » 45 patients have now had their implant for more than 3 years and 15 patients more than 4 years
- » Appointment of Dr. Michael A Kelly as special study advisor for the US IDE study
- » Episurf Medical's knee products were approved for marketing and sale in Spain
- » Episurf Medical entered into a distribution agreement in Hong Kong and established subsidiary in the US
- » Katarina Flodström assumed the position Chief Regulatory Officer with responsibility for regulatory affairs, quality affairs and Intellectual property
- » Episurf Medical released new CE-marked joint visualisation tool based on AI
- » Episurf Medical has received initial feedback from the US FDA on the IDE application for the Episealer® knee Implant
- » Episurf Medical expanded into the Polish Market » Promising clinical results from use of Episealer® was accepted for presentation at the annual meeting of the Australian Knee Society in October
- » Clinical outcome for Episealer® was presented at the annual meeting of the European Orthopaedic Research Society (EORS) In Galway, Ireland In September
- » Patent approvals in Japan, US, Canada and Australia for Episurf Medical

- » Episurf Medical announced that the company had received approval from the US Food and Drug Administration (FDA) for its Investigational Device Exemption (IDE) application to initiate a clinical study on the Episealer® knee implant in the United States
- » Episurf Medical executed a directed share issue, raising SEK 13.2m. Through the directed share issue, the company gained a US shareholder among the largest shareholders and several existing shareholders increased their holdings
- » Niles Noblitt was appointed Senior Advisor to Episurf Medical
- » Episurf Medical announced the start of a new investigator-initiated clinical study conducted by Prof. H. Vandenuecker at the University hospital in Leuven, Belgium
- » Clinical outcome for Episealer® was presented at the annual meeting of the Danish Orthopaedic Society (DOS) in Copenhagen in October
- » New Chinese and US patent approvals for Episurf Medical
- » Episurf Medical was informed about the intention of its largest shareholder Serendipity Ixora AB to wind-up its operations and in conjunction thereto distribute its holdings of Episurf shares to its shareholders

Significant events after the end of the financial year

- » Episurf Medical announced the start of a comparative investigator-initiated clinical study performed at the Julius Wolff Institute, Charité University Hospital, Berlin
- » New Australian and Canadian patent approvals for Episurf Medical
- » Clinical results for Episealer® was presented at a German clinical congress in February
- » Episurf Medical reached milestone of 500 implants
- » Progress for Episurf medical in initiation of Episealer® Knee IDE study

Employees

At 31 December 2018, the Group had 24 employees (26), of whom employees in the parent company Episurf Medical AB totaled to 11 (13). Personnel costs amounted to SEK 27.3m (33.3) in the Group and SEK 12.6m (13.2) 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, up-to-date 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 need, 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 9.7m (7.4) for the financial year of which SEK 4.3m (3.7) are related to capitalised development costs, remaining investments relates to patents. Investments in tangible assets amounted to SEK -m (0.0) for the financial year.

Investments in the parent company

Investments in intangible assets, capitalised development costs, amounted to SEK 4.3m (3.7) for the financial year. Investments in tangible assets amounted to SEK -m (-) for the financial year.

Consolidated income and expenses

Net sales

Consolidated net sales for the period from 1 January 2018 to 31 December 2018 amounted to SEK 4.0m (2.5). The increased net sales is a result from increased clinical acceptance and market penetration in prioritized markets. the Nordic countries, Benelux, Germany and the United Kingdom.

Expenses

The Group's expenses for the period from 1 January 2018 to 31 December 2018 amounted to SEK 61.8m (64.2). The result for 2017 was negatively impacted by expenses of approximately SEK 3 million related to the previous CEO. One new employee have been hired since last December and three have left the company.

Profit

The consolidated operating loss for the period from 1 January 2018 to 31 December 2018 was SEK -57.5m (-61.2). The loss after financial items was SEK -57.8m (-61.1). 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 2018 amounted to SEK 28.3m (71.3). Cash flow from operating activities before changes in working capital was SEK -52.2m (-56.8). Consolidated equity at yearend amounted to SEK 44.8m (85.6) and the equity ratio was 81.8 per cent (91.7).

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 2018 to 31 December 2018 reached SEK 0.4m (0.2) and refers to intra-group revenues. Operating expenses amounted to SEK 29.4m (30.0). The operating loss was SEK -29.0m (-29.7) and the loss after financial items was SEK -29.7m (-29.7). The parent company's cash and cash equivalents at year end amounted to SEK 17.6m (62.5).

Proposed appropriation of earnings

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

mSEK	
Share premium reserve	344.9
Accumulated deficit	-180.9
Loss for the year	-29.7
Total	134.3

The Board proposes that the earnings be appropriated so that SEK 134.3m is carried forward to new account. 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 disclosures.

Dividend

The Board of Directors and the CEO propose that no dividend be paid for the financial year from 1 January 2018 to 31 December 2018.

The Group's future development and continued operations

The Group's fifth product, the Epioscopy® Damage Assessment Tool, received a CE-mark in January 2016 and an updated version received a CE-mark in September 2018. Episurf Medical has apart from that focused on the company's current other four approved medical devices Episealer® Condyle Solo, Episealer® Trochlea Solo, Episealer® Femoral Twin and Epiguide® MOS. The introduction in Europe is planned to continue during 2019. A new product, the ankle implant Episealer® Talus is further planned to be introduced. The goals for 2019 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 conduction of the first surgeries with Episealer® Talus. Another high priority is the next step of the US strategy, where the initiation of the FDA-approved IDE-study is approaching. Episurf Medical is currently recruiting hospitals in the US and Europe to participate, performing training of the new Episealer® surgeons and preparing for the first enrolments. 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. Additional strengthening within the fields of health economic studies, regulatory affairs and reimbursement are also prioritised areas.

Together, all of this 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 2019. 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 on the on the recruitment rate for clinics and patients.

During 2019, management estimate that expenses for market initiatives in the USA will result in increased expenses while costs in the European operations will decrease.

As of December 31, 2018, the group had SEK 28.3m in cash and cash equivalents. To assure financing of continued operations, a financing agreement with European Select Growth Opportunities Fund was entered into in February and decided on the Annual General Meeting in April 2018. The agreement provides the company with access to SEK 70m over a 36month period of which SEK 7m was utilised during the second quarter 2018. The company thus has SEK 63m left to use. See more information about the financing agreement below and on the Company's website.

During the fourth quarter, the company carried out a directed share issue to a number of selected investors, including Niles Noblitt (one of the founders of Biomet) and the existing shareholder Rhenman Healthcare Equity L/S. In total, SEK 13.2m before transaction costs was contributed to Episurf.

As the company, in spite of the financing measures outlined above, within the next 12 months has additional financing needs that have not yet been secured, the Board is continuously working on evaluating various financing options to ensure continued operation. It is the Board's assessment that the company has good prospects of securing future financing either with the support of, for example, a new credit facility or through a new share issue.

Financing Agreement

To assure financing of continued operations, a financing agreement with European Select Growth Opportunities Fund ("ESGOF") was entered into in February and approved at the Annual General Meeting in April 2018. The agreement provides the company with access to SEK 70m over a 36month period in form of convertible debt securities divided into a number of tranches.

In connection with each tranche of convertibles, warrants are also issued to ESGOF.

When convertibles and warrants are issued to ESGOF, warrants are also issued free of charge to existing shareholders. Full utilization of these warrants would entail an additional SEK 70 million being added to the company.

Key terms of the financing agreement

- » The notes have a principal amount of SEK 50.000 each, they bear no interest and have a maturity of 12 months from the date of the registration of their issuance with the Swedish Companies Registration Office. During their term, the investor may request to convert some or all of the notes at a variable conversion price representing an 8% discount to the lowest daily volume weighted average price over the last 15 trading days during which the investor has not sold any share on the market prior to the conversion date.
- » Upon such conversion request, Episurf Medical has the option to remit, at its discretion, cash, shares in Episurf Medical or a combination of both. This characteristic will enable Episurf Medical to manage the potential dilution resulting from the notes.
- » Episurf Medical pay to the investor a commitment fee equal to 4% of the aggregate principal amount of the notes issued under the requested tranche.
- » In case of an event of default, each outstanding note will accrue interest at a rate of 15%.

Main characteristics of the warrants issued to ESGOF

- » ESGOF receives warrants without further remuneration in connection with the issuance of a tranche of convertibles. The number is determined based on the current stock price in connection with the execution of the tranche.
- » The warrants have a term of five (5) years from the date of the registration of their issuance with the Swedish Companies Registration Office and will immediately be detached from the notes. 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 new tranche.

Follow-up table, financing agreement

Financing, SEKm	Total	Used	Remaining
European Select Growth Opportunities Fund	70.0	7.0	63.0

Convertibles

Tranch	Amount before costs	Date	Number of notes	Number utilised	Number of outstanding notes
KV1	SEK 7m	2018-05-23	140	82	58

Summary of transactions

Received cash from issue of convertible debentures	7.0
Transaction costs	-0.3
Net proceeds	6.7
Amount classified as equity	-0.5
Converted debentures	-4.1
Accrued interest	0.6
Reported value of debt as at December 31, 2018	2.8

Warrants

Tranch	Registration date	Term to maturity	Strike price	Number of warrants outstanding	Number of utilised	Number of outstanding
KV1/TO4B	2018-05-23	5 year	6,10	2,279,002	0	2,279,002

Key terms of warrants issued to existing shareholders

- » In connection with the issue of convertible bonds and warrants to ESGOF, warrants are also issued free of charge to existing shareholders, the number is determined on the basis of the current share price in connection with the completion of the tranche.
- » The shareholder options have the same characteristics as the warrants and are admitted to public trading.

Use of convertibles and warrants

» The first tranche was conducted in the second quarter of 2018 as a targeted issue of SEK 7m through the issuance of 140 convertibles of 1.147.540 associated warrants to ESGOF. In connection with this, 1.131.462 warrants were also issued to the shareholders. All warrants have a redeeming price of SEK 6.10. See table below for follow-up of number of outstanding and utilised convertibles and warrants.

Guidelines for remuneration to senior executives

Remuneration The annual general meeting held on 9 April 2018 resolved on the following guidelines for remuneration to the executives of Episurf Medical for the period until the annual general meeting of 2019. Compensation and conditions of employment for the senior executive, by which is meant the CEO, the CFO, the COO, the Head of Quality & Regulatory affairs, Sales director and Marketing director. December 31, 2018 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 2019 that will be presented by the Board to the AGM on 8 April 2019 for approval are identical to the current guidelines. During the financial year 2018, the company's CEO Pål Ryfors has received a total amount of SEK 2.3m 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 Sales Director, Göran Martinsson, a mutual notice period of four months applies for the termination of employment of the COO, Jeanette Spångberg and a mutual notice period of three months applies for the termination of employment of the CFO, Veronica Wallin, the Chief Regulatory Officer, Quality Affairs and Intellectual Property, Regulatory Affairs, Quality affairs and Intellectual property, Katarina Flodström and the Marketing Director, Fredrik Zetterberg. The COO, CFO, Chief Regulatory Officer, Quality Affairs and Intellectual Property, Quality affairs and Intellectual property, 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 period of SEK 0.6m (0.7).

As a technical measure in order to meet European Select Growth Opportunities Funds demand for immediate access to its shares, certain shareholders, during a transitional period, lend shares to the issuing agent engaged for this agreement. The Chairman and Members of the board's fees were agreed by the AGM and is shown below.

The Chairman receive SEK 0.4m, Wilder Fulford and Laura Shunk receive remuneration of SEK 0.2m, Leif Ryd and Christian Krüeger receive remuneration of SEK 0.1m respectively. In total, the board fees amount to SEK 1.0m (1.1).

Significant risks and uncertainties

Clinical trials Episurf Medical has been conducting a clinical trial in humans since 2012. This study is focused on implementation of tests on humans for Episealer® Condyle Solo, where the main study parameters are joint pain and function. The collaboration with different researches and clinics are very important for Episurf Medical's business. Clinical trials are of large importance within the area of repair of cartilage damages in joints. The results for 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 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 commercialize products and the prospect of potential future sales is dependent on, among other things, the level of reimbursement which the company's may receive for its 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 does not receive compensation in some markets from the national insurance systems and no clinical acceptance of the methods are 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. 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 the level of reimbursement for Episurf Medical's future products will be lower than expected or be non-existent, 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 not can 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,

Benelux, Germany and the United Kingdom. Should Episurf Medical not successfully succeed to establish new sales organizations or maintain or develop its current sales organization 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 organization becomes more time consuming and costly than Episurf Medical has estimate, 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 products 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 company's 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 varying changing requirements

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 (Food and Drug Administration) 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 materialize, it could have a material adverse effect on the company's business, financial position and results of operations.

IPR

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 in the course of its research or in the medicinal devices Episurf Medical is developing and commercialising or intends to develop and commercialize 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 lose 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 current and 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. 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 30,549,495, of which 6,363,577 were class A and 24,185,918 were class B shares. The total number of shares at year-end 2018 was 31,631,169, of which 5,221,662 were class A shares and 26,409,507 were class B shares. The total number of votes was 42,074,493.

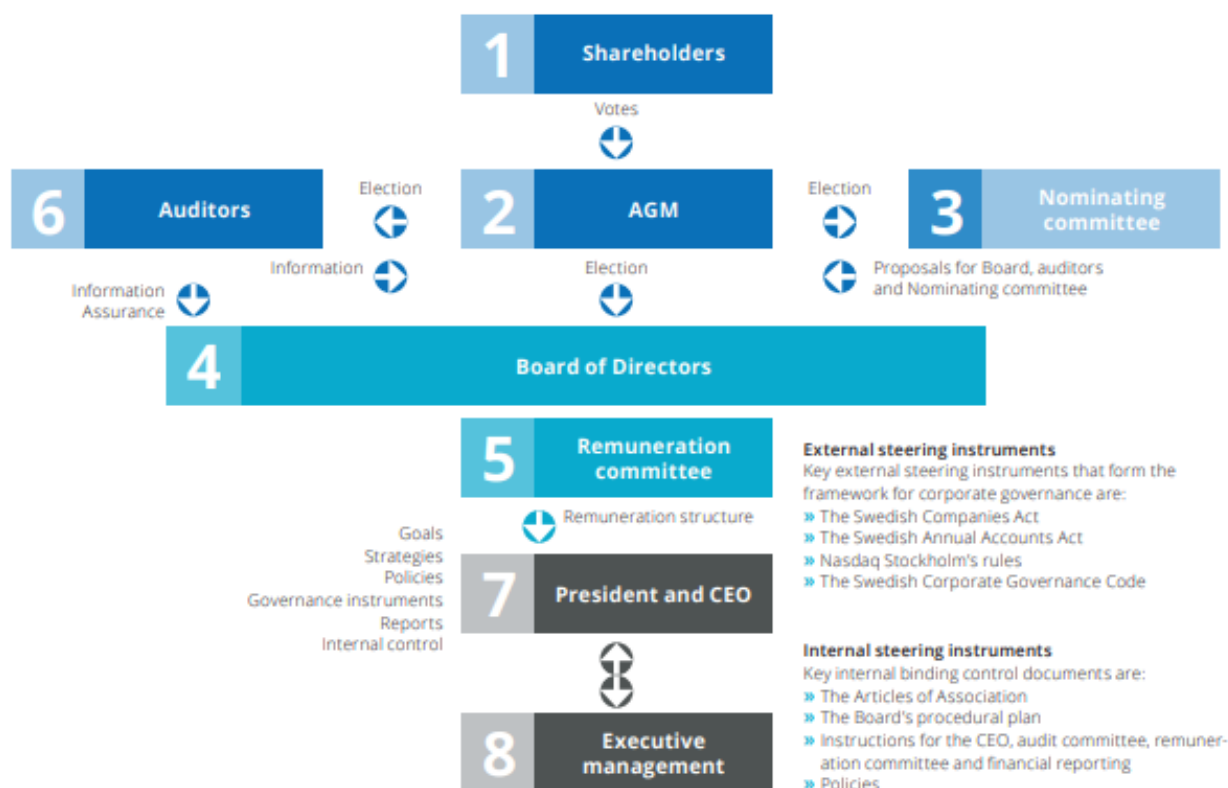
The registered share capital at 31 December 2018 amounted to SEK 9,497,382.90 with a quota value of SEK 0.30 per share. SEK 987,898.49 was not registered share capital as of December 2018 and was registered with the Swedish Companies Registration Office on January 9, 2019. According to the Articles of Association 31 December 2018, the share capital shall amount to no less than SEK 4,500,000 and no more than SEK 18,000,000, divided between no fewer than 15,000,000 shares and no more than 60,000,000 shares. The number of shareholders at year-end was 3,478 (3,070). The ten largest shareholders in Episurf Medical in terms of voting power held shares corresponding to 46.3 per cent (48.0) of the share capital and 58.5 per cent (61.7) of the votes. The largest shareholder, Serendipity Ixora AB, held shares corresponding to 14.6 per cent (15.3) of the share capital and 32.8 per cent (32.3) of the votes.

Corporate governance report

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 COMPANY'S CORPORATE GOVERNANCE is regulated by the Articles of Association, the Swedish Companies Act,

Governance structure



Nasdaq Stockholm's Rules for Issuers, which include the Swedish Corporate Governance Code (the Code), and other applicable laws and rules.

Episurf Medical's Articles of Association can be downloaded from the company's website (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.

Episurf Medical complies with the Code with deviation for the audit committee. This deviation is explained in detail below. Since the time of listing, the company has not committed any violations of Nasdaq Stockholm's Rules for Issuers or generally accepted practice in the stock market.

1 Share and shareholders

Episurf Medical's shares are issued in two classes, class A and class B. 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. 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. The total number of shares at year-end 2018 was 31.631.169, of which 5.221.662 were class A shares and 26.409.507 were class B shares. The total number of votes amounted to 42.074.493.

The number of shareholders at year-end was 3.478 (3.070). The ten largest shareholders in Episurf Medical in terms of voting power held shares corresponding to 46.3 per cent (48.0) of the share capital and 58.5 per cent (61.7) of the votes. The largest shareholder, Serendipity Ixora AB, held shares corresponding to 14.6 per cent (15.3) of the share capital and 32.8 per cent (32.3) of the votes. For further information about the share, shareholders and ownership structure, see pages 35–37 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).

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 2018

The AGM on 8 April 2018 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 100.000 to each member of the Board, however that Wilder Fulford and Laura Shunk, shall receive an annual fee of SEK 200.000 and the Chairman of the Board of Directors shall receive an annual fee of SEK 400.000. the total is therefore SEK 1.000.000. 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 2019 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.
- » To Authorise the Board of Directors to resolve on new issues of shares for the period until the 2019 annual general meeting.
- » In accordance with the proposal by the Board of Directors, the Meeting resolved on (i) adoption of an employee stock option and warrant programme, (ii) an issue of warrants of series 2018/2021(A), and (iii) an issue of warrants of series 2018/2021(B) and approval of transfers of warrants of series 2018/2021(B).

Extraordinary general meeting 2018

The extraordinary general meeting on 7 December 2018 resolved to approve the Board of Director's resolution on a directed new share issue of series B, and a directed new issue of warrants of series 2018/2020.

AGM 2019

The 2019 AGM will be held in Stockholm on 8 April 2019. 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 2018 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 2019 AGM

Dennis Stripe, Chairman of Episurf Medical AB

Saeid Esmaeilzadeh, Representing Serendipity Ixora AB

Peter Ragnarsson, Representing LMK Stiftelsen

Leif Ryd, Representing Gile Medicinkonsult AB

Saeid Esmaeilzadeh 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 2019 has held two meetings. 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 2018 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 (SEKm)	Meeting attendance	Independent	
						From the company	From shareholders
Dennis Stripe	Board Chairman	1957	2016	0.4	17/17	Yes	Yes
Christian Krüeger	Board member	1966	2016	0.1	16/17	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 on 6 April 2018. 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 2018

The Board held seventeen meetings in 2018. 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, organization, risk and internal control, financial reporting and monitoring, financial position and investments. In 2018 the Board devoted special attention to issues related to marketing, sales and financing.

Evaluation of the Board's work was conducted in December 2018 and was presented written to the Board and the Nomination Committee in February 2019 and then orally for the Board February 12, 2019. Evaluation of the Board's executive director Pål Ryfors, was conducted in February 2019.



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 9 April 2018, 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 and Laura Shunk and SEK 0.1m to Leif Ryd and Christian Krüeger, respectively. It was further resolved that no remuneration shall be paid for committee work. During the financial year 2018, the total remuneration to the members of the board of directors amounted to SEK 1.0m distributed in accordance with the table on page 52.

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 2018, 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 2018 AGM elected the auditing firm of KPMG AB as the company's independent auditor to serve until the end of the 2019 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 2018 the executive management consisted of Pål Ryfors (CEO), Veronica Wallin (CFO), Jeanette Spångberg (COO), Fredrik Zetterberg (Marketing Director), Göran Martinsson (Sales Director) and Ladan Amiri (Head of Quality & Regulatory affairs).

Ladan Amiri left the Company during the year and Katarina Flodström was appointed Chief Regulatory Officer, quality affairs and intellectual property in June 2018.

Remuneration to the CEO and management

THE COMPANY'S AGM ON 9 April 2018 resolved to implement the following guidelines for remuneration to senior executives for the period until the 2019 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 Chief Regulatory Officer, Regulatory affairs, Quality affairs and Intellectual property, the Sales Director and the Marketing Director December 31, 2018, 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 per cent 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.

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 realized, 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 2018.



Dennis Stripe
Chairman of the Board since 2016
Shareholding 17,900 B-shares. 663 TO4B (warrants)
Born 1957

Education and experience: Mr. Dennis Stripe has almost 40 years of experience from various positions in management, sales and marketing on a global basis. When joining Kendall Healthcare Products in 1983, Mr. Stripe started a career within the healthcare industry lasting 33 years. In 1991, Mr. Stripe joined Smith & Nephew as a Senior Product Manager. During his time at Smith & Nephew, Mr. Stripe held various senior positions with Marketing, ending as a Group Marketing Director within the Orthopedic Division. Following a successful career at Smith & Nephew, Mr. Stripe joined the Spine Division of Stryker Corporation in 1996 and remained there until 2008. At Stryker Corporation, Mr. Stripe held several senior management roles on a global basis, including the Vice President of Global Marketing. In 2008, Mr. Stripe joined OrthoHelix Surgical Designs, a medical technology company focusing on implants and instruments for reconstruction surgery. Mr Stripe remained at OrthoHelix Surgical Designs until 2013 and served as Chief Executive Officer and as member of the Board of Directors for five years. OrthoHelix Surgical Designs was ultimately sold to Nasdaq listed company Tornier N.V., a transaction led by Mr. Stripe.

Mr. Stripe is currently a key executive of California based Compliant Innovations, a company focusing on software solutions for the healthcare industry, as well as a member of the Board of Directors of Central-Insurance Companies and Medshape.

Current positions: Member of the Board of directors of Medshape Inc., Central Insurance Companies and advisor to Compliant Innovations Inc.

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



Wilder Fulford
Board member since 2016
Shareholding –
Born 1958

Education and experience: Dr. Wilder Fulford is currently CEO of The Fulford Group, which he founded 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. Dr Fulford has advised the Boards, management and owners of companies in diverse industries on M&A, corporate finance and other strategic transactions for over 25 years. Prior to founding The Fulford Group, Dr Fulford founded the London office of Torrey Partners, a specialist life sciences advisory firm, in 2011. 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 advised 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 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 100,000 B-shares in person. and 279,945 A-shares and 142,954 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.

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 –

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:

Member of the board and CEO of LMK Venture Partners AB and LMK Venture Partners Utveckling AB. Member of the board of Solnaberg Property AB (publ), Bynk AB, Mälarsåsen AB (publ), Venaticus Capital AB, Bostadsrättsföreningen Härolden nr 38, Krueger Liljefors Holding AB, Mälarsåsen Fastigheter i Märsta AB, Mälarsåsen Fastigheter i Stockholm AB and Solnaberg Bladet 3 ProCo AB. Deputy member of the board of LMK Hotels & Real Estate AB, LMK Ventures AB, Krueger Liljefors Partners 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 50,750 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.

Current positions: Board Member of SCI Engineered Materials, Co, and a member of Extremity Development Corporation.

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

Executive management

**Pål Ryfors****CEO since 2017****Shareholding** 1,016,393 B-shares (350,000 of these shares are lent out to ESGOF)**Employee stock option** 71,450**Warrants** 39,681**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.

Most recently, he was the CFO of Marginalen Bank, a Swedish bank employing some 350 people, where Ryfors was responsible for the strategic financial planning and management, as well as leading the financial operations and implementing corporate development initiatives. Previously, Ryfors was Head of Group Controlling at Hoist Finance. Prior to joining Hoist Finance, Ryfors was an investment banker at Societe Generale, where he joined after holding several leading positions in the restructuring of the Swedish operations of Kaupthing Bank.

Other appointments: Board member Aros Kapital.

**Veronica Wallin****CFO since 2017****Shareholding** 4,000 B-Shares**Employee stock option** 44,350**Warrants** 24,748**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: Board member Bostadsrättsföreningen Kettingen 1.

**Jeanette Spångberg****COO since 2011****Shareholding** 9,422 B-Shares**Employee stock option** 71,350**Warrants** 8,333**Born** 1973

Education and experience: Jeanette Spångberg has a Bachelor of Science in Construction Engineering, Information Technology and Environment. From 1999 to 2008. Jeanette worked as Production Manager at Nobel Biocare ProCera AB, before being promoted to Technical Manager in 2008. At Nobel Biocare, Jeanette was, among other things, involved in building a quality system for ISO 9001 certification.

Other appointments: –



Katarina Flodström

Chief Regulatory Officer, Quality Affairs and Intellectual Property since 2018

Shareholding 25,000 B-Shares (of which 7,000 is family members)

Employee stock option 42,400

Warrants 11,755 (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 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: –



Göran Martinsson

Sales Director since 2014

Shareholding 47,680 B-Shares (of which 7,340 is family members)

Employee stock option 53,550

Warrants 22,413 (of which 271 is family members)

Born 1959

Education and experience: Göran Martinsson has more than 30 years of experience from senior management roles in various technology companies including the

companies in the medical technology sector. Prior to joining Episurf Medical in August 2014, Göran worked at companies such as ArthroCare and Merivaara.

Other appointments: –



Fredrik Zetterberg

Marketing Director since 2017

Shareholding 4,000 B-Shares

Employee stock option 35,450

Warrants 12,700

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: –

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Five-year overview – Group

mSEK	Jan-Dec 2018	Jan-Dec 2017	Jan-Dec 2016	Jan-Dec 2015	Jan-Dec 2014
INCOME STATEMENT					
Operating income	4.3	3.1	2.7	6.6	2.3
Operating expenses	-61.8	-64.2	-64.4	-50.7	-35.6
Operating loss	-57.5	-61.2	-61.7	-44.0	-33.3
Net interest income	-0.3	0.1	0.0	0.0	0.3
Loss before tax	-57.8	-61.1	-61.7	-44.0	-32.9
Income tax expense	--	0.0	--	--	--
Loss for the year	-57.8	-61.1	-61.7	-44.0	-32.9
ASSETS					
Intangible assets	21.1	16.0	12.6	11.0	5.9
Property, plant and equipment	0.1	0.2	0.4	0.4	0.4
Other current assets	5.3	5.7	5.0	2.8	2.4
Cash and cash equivalents	28.3	71.3	42.3	104.0	34.5
Total assets	54.8	93.3	60.3	118.2	43.2
EQUITY AND LIABILITIES					
Equity	44.8	85.6	48.7	109.9	38.8
Non-current liabilities	0.0	0.0	0.0	--	--
Current liabilities	10.0	7.7	11.6	8.3	4.4
Total equity and liabilities	54.8	93.3	60.3	118.2	43.2

Five-year overview – Group. cont'd.

mSEK	Jan-Dec 2018	Jan-Dec 2017	Jan-Dec 2016	Jan-Dec 2015	Jan-Dec 2014
CASH FLOW STATEMENT					
Cash flow from operating activities	-52.3	-61.4	-56.1	-38.0	-31.7
Cash flow from investing activities	-9.7	-7.5	-5.6	-7.4	-2.9
Cash flow from financing activities	19.1	97.8	--	114.9	0.2
Cash flow for the year	-43.0	29.0	-61.7	69.5	-34.4
KEY RATIOS					
Share price at year-end	2.9	5.4	15.0	17.5	35.7
Earnings per share (weighted average)	-1.87	-2.18	-3.24	-3.52	-2.98
Equity per share	1.42	2.80	3.05	6.89	4.88
Number of shares at end of year	31 631 169	30 549 495	15 949 804	15 963 305	7 956 579
Average number of shares during the year	30 869 741	27 987 331	19 003 941	12 504 417	11 059 418
Equity ratio, %	81.8%	91.7%	80.8%	93.0%	89.8%
Number of employees at the end of the year	24	26	27	18	14
Cash and cash equivalents at the end of year	28.3	71.3	42.3	104.0	34.5
Cash flow for the year	-43.0	29.0	-61.7	69.5	-34.4
Investments in intangible assets	9.7	7.4	5.4	7.2	2.8
Investments in property, plant and equipment	--	0.0	0.0	0.1	0.0

Consolidated income statement

mSEK	Note	Jan-Dec 2018	Jan-Dec 2017
Operating income			
Net sales	5,6	4.0	2.5
Other operating income	6	0.3	0.6
Total operating income		4.3	3.1
Operating expenses			
Merchandise		-3.3	-2.3
Other expenses	8	-36.1	-31.9
Personnel costs	9	-27.3	-33.3
Capitalised development expenditure		9.7	7.4
Depreciation of equipment and non-current assets		-4.8	-4.2
Total operating expenses		-61.8	-64.2
Operating loss		-57.5	-61.2
Financial income, other	7	0.3	0.1
Financial expenses, other	7	-0.7	-0.0
Loss after financial items		-0.3	0.1
Loss after tax		-57.8	-61.1
Income tax expense	10	-0.0	0.0
Loss for the year		-57.8	-61.1
Earnings per share before and after dilution*		-1.87	-2.18

* For more information, see note 9.

Consolidated statement of comprehensive income

mSEK	Note	Jan-Dec 2018	Jan-Dec 2017
Loss for the year		-57.8	-61.1
Items that may be reclassified to profit/loss			
Exchange differences arising from the translation of foreign subsidiaries		-0.1	-0.0
Total comprehensive income for the year		(57.9)	-61.1
<i>The year's loss and comprehensive income attributable to</i>			
Owners of the parent		-57.9	-61.1
Average number of shares		30 869 741	27 987 331

Consolidated balance sheet

mSEK	Note	31 Dec 2018	31 Dec 2017
ASSETS			
Non-current assets			
Capitalised development costs	11	9.5	6.8
Patents	11	11.6	9.3
Total intangible assets		21.1	16.0
<i>Property, plant and equipment</i>			
Equipment	12	0.1	0.2
Total property, plant and equipment		0.1	0.2
Total non-current assets		21.2	16.3
Current assets			
Inventories	16	1.5	1.7
Trade receivables	15	0.8	1.0
Other receivables		1.7	1.2
Deferred expenses and accrued income	17	1.3	1.8
Cash and bank balances		28.3	71.3
Total current assets		33.6	77.0
TOTAL ASSETS		54.8	93.3
EQUITY			
Equity attributable to owners of the parent			
Share capital	18	10.5	9.2
Other contributed capital	18	346.0	330.4
Reserves		0.5	0.6
Accumulated deficit incl. Loss for the year		-312.1	-254.6
Total equity		44.8	85.6
LIABILITIES			
Non-current liabilities			
Non-current liabilities		0.0	0.0
Total long-term liabilities		0.0	0.0
Current liabilities			
Trade payables		1.6	2.5
Current interest-bearing liabilities	19	2.8	--
Other liabilities	20	1.6	1.4
Accrued liabilities and deferred income	21	4.0	3.8
Total current liabilities		9.9	7.7
Total liabilities		10.0	7.7
TOTAL EQUITY AND LIABILITIES		54.8	93.3

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	
Opening equity January 1, 2017	4.8	237.0	0.6	-193.7	48.7
Total					
Total comprehensive income for the period			-0.0	-61.1	-61.1
Total comprehensive income			-0.0	-61.1	-61.1
Transactions with shareholders					
New share issue, net after issue expenses*	4.4	93.3			97.7
Options issued to staff				0.3	0.3
Total transactions with shareholders	4.4	93.3		0.3	98.0
Closing equity December 31, 2017	9.2	330.4	0.6	-254.6	85.6
Opening equity January 1, 2018	9.2	330.4	0.6	-254.6	85.6
Total					
Total comprehensive income for the period			-0.1	-57.8	-57.9
Total comprehensive income			-0.1	-57.8	-57.9
Transactions with shareholders					
Directed share issue, net after issue expenses**	1.0	11.3			12.3
Warrant issued		0.5			0.5
Issue in-kind, for conversion of debt***	0.3	3.8			4.1
Options issued to staff				0.3	0.3
Total transactions with shareholders	1.3	15.6		0.3	17.2
Closing equity December 31, 2018	10.5	346.0	0.5	-312.1	44.8

* Issue expenses amounts to SEK 11.8m

** Issue expenses amounts to SEK 0.9m. The directed share issue, which was carried out in December 2018, was registered at the Swedish Companies Registration Office on January 9, 2019, and the company's shares and votes increased by 3,290,210

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

Consolidated cash flow statement

mSEK	Note	Jan-Dec 2018	Jan-Dec 2017
Operating activities			
Operating loss		-57.5	-61.2
Adjustments for items not included in cash flow			
Depreciation		4.8	4.2
Employee stock option expenses		0.2	0.1
Interest received		0.3	0.1
Interest paid		-0.0	-0.0
Cash flow from current operations before change in working capital		-52.2	-56.8
Change in working capital			
Decrease/increase in inventory		0.2	-0.6
Decrease/increase in trade receivables		0.2	-0.4
Decrease/increase in current receivables		0.8	0.3
Decrease/increase in current liabilities		-1.3	-3.9
Change in working capital		-0.1	-4.6
Cash flow from current operations		-52.3	-61.4
Investing activities			
Investments of intangible fixed assets		-9.7	-7.4
Investments of property, plant and equipment		--	-0.0
Cash flow from investing activities		-9.7	-7.5
Financing activities			
Investment in warrants		0.1	0.1
New share issue		12.3	97.7
Issue of convertibles*		6.7	--
Cash flow from financing activities		19.1	97.8
Cash flow for the period		-43.0	29.0
Cash and cash equivalents at beginning of period		71.3	42.3
Cash and cash equivalents at end of period		28.3	71.3

*Refers to the utilised part of the financing agreement net for transaction costs

Parent Company income statement

mSEK	Note	Jan-Dec 2018	Jan-Dec 2017
Operating income			
Net sales	6	0.4	0.2
Total income		0.4	0.2
Operating costs			
Other external expenses	8	-19.0	-19.2
Personnel costs	9	-12.6	-13.2
Capitalised development expenditure		4.3	3.7
Depreciation of equipment and non-current assets		-2.1	-1.4
Total operating costs		-29.4	-30.0
Operating loss		-29.0	-29.7
Financial income, other	7	0.0	0.1
Financial expenses, other	7	-0.7	-0.0
Results from net financial items		-0.7	0.1
Loss before contribution and tax		-29.7	-29.7
Loss before tax		-29.7	-29.7
Tax on income for the period	10	--	--
Loss at end of the period		-29.7	-29.7

Parent Company statement of comprehensive income

mSEK	Note	Jan-Dec 2018	Jan-Dec 2017
Net profit		-29.7	-29.7
Other comprehensive income for the period:			
Other comprehensive income for the period, net of tax		--	--
Total comprehensive income for the period		-29.7	-29.7

Parent Company balance sheet

mSEK	Note	31 Dec 2018	31 Dec 2017
ASSETS			
Fixed assets			
Intangible fixed assets			
Capitalised development costs	11	9.5	7.1
Total intangible fixed assets		9.5	7.1
Tangible fixed assets			
Equipment	12	0.0	0.1
Total tangible fixed assets		0.0	0.1
Financial assets			
Shares in group companies	13	106.8	78.3
Long-term receivables from group companies	14	24.0	20.0
Total financial assets		130.8	98.2
Total fixed assets		140.3	105.5
Current assets			
Current receivables			
Other receivables		1.3	0.5
Prepaid expenses and accrued income	17	0.6	0.8
Total short term receivables		1.9	1.3
Cash and cash equivalents		17.6	62.5
Total current assets		19.5	63.8
TOTAL ASSETS		159.7	169.3
EQUITY AND LIABILITIES			
Equity			
Equity Restricted equity			
Share capital	18	10.5	9.2
Development fund		7.9	4.5
Total restricted equity		18.3	13.7
Unrestricted equity			
Share premium reserve	18	344.9	329.3
Loss brought forward		-180.9	-148.0
Loss for the period		-29.7	-29.7
Total unrestricted equity		134.3	151.7
Total equity		152.6	165.3
NON_CURRENT LIABILITIES			
Non-current liabilities		--	0.0
Total long-term liabilities		--	0.0
Current liabilities			
Trade payables		0.4	0.9
Current interest-bearing liabilities	19	2.8	--
Other liabilities	20	0.7	0.6
Accrued liabilities and deferred income	21	3.3	2.5
Total current liabilities		7.1	4.0
Total liabilities		7.1	4.0
TOTAL EQUITY AND LIABILITIES		159.7	169.3

Parent Company Statement of changes in equity

mSEK	Share capital	Development fund	Share premium reserve	Loss brought forward	Loss for the period	Total equity
Opening equity January 1, 2017	4.8	1.1	235.8	-110.4	-34.1	97.2
Comprehensive loss for the period						
Loss for the period					-29.7	-29.7
Disposition according to AGM						
Loss brought forward				-34.1	34.1	--
Development fund		3.5		-3.5		--
Total comprehensive loss for the period		4.5		-148.0	-29.7	67.5
Transactions with shareholders						
New share issue, net after issue expenses*	4.4		93.3			97.7
Warrants			0.1			0.1
Total transactions with shareholders	4.4		93.5			97.8
Closing equity December 31, 2017	9.2	4.5	329.3	-148.0	-29.7	165.3
Opening equity January 1, 2018	9.2	4.5	329.3	-148.0	-29.7	165.3
Comprehensive loss for the period						
Loss for the year					-29.7	-29.7
Disposition according to AGM						
Loss brought forward				-29.7	29.7	--
Development fund		3.3		-3.3		--
Total comprehensive loss for the period	9.2	7.9	329.3	-181.0	-29.7	135.7
Transactions with shareholders						
Directed share issue, net after issue expenses**	1.0		11.3			12.3
Warrant issued			0.5			0.5
Issue in-kind, for conversion of debt***	0.3		3.8			4.1
Options issued to staff				0.1		0.1
Total transactions with shareholders	1.3		15.6	0.1		16.9
Closing equity December 31, 2018	10.5	7.9	344.9	-180.9	-29.7	152.6

* Issue expenses amounts to SEK 11.8m

** Issue expenses amounts to SEK 0.9m. The directed share issue, which was carried out in December 2018, was registered at the Swedish Companies Registration Office on January 9, 2019, and the company's shares and votes increased by 3,290,210

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

Parent Company cash flow statement

mSEK	Note	Jan-Dec 2018	Jan-Dec 2017
Current operations			
Operating loss		-29.0	-29.7
Adjustments for items not included in cash flow		0.0	0.0
Depreciation		2.1	1.4
Interest received		0.0	0.1
Interest paid		0.0	0.0
Change in non-current liabilities		0.0	0.0
Cash flow from current activities before changes in working capital		-26.9	-28.3
Changes in working capital			
Decrease/increase in current receivables		0.1	0.1
Decrease/increase in current liabilities		-0.4	-6.6
Total changes in working capital		-0.2	-6.5
Cash flow from operating activities		-27.2	-34.8
Cash flow from investing activities			
Investments of intangible fixed assets		-4.3	-3.7
Changes in financial assets		-32.5	-36.9
Cash flow from investing activities		-36.8	-40.6
Cash flow from financing activities			
Warrants		0.1	0.1
New share issue		12.3	97.7
Issue of convertibles*		6.7	--
Cash flow from financing activities		19.1	97.8
Cash flow for the year		-44.9	22.4
Cash and cash equivalents at beginning of period		62.5	40.1
Cash and cash equivalents at end of period		17.6	62.5

*Refers to the utilised part of the financing agreement net for transaction costs.

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 7 March 2019. 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 with the exception of financial instruments, which are stated at fair value.

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 periods 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.

Also, Standards, revisions and interpretations of existing standards that are not yet effective and have not been applied early by Episurf Medical AB (publ) are described below.

At the time of preparation of the consolidated financial statements at 31 December 2018, a number of standards and interpretations had been published that are applicable to Episurf Medical AB (publ) but are not yet effective.

Below is a description of new and revised standards and interpretations that have been published but are effective later than 31 December 2018.

IFRS 16, Leases

IFRS 16, Leases that replace the current IAS 17. Leases and related interpretations came into force for the financial year that started on January 1, 2019. The standard requires lessees to recognise assets and liabilities for all leases unless the lease term is 12 months or less or the underlying asset has a low value.

Episurf Medical will apply the new standard by using the modified retroactive transition method, which means that the comparative figures will not be recalculated. The cumulative effect of applying IFRS 16 will be reported on 1 January 2019. Long term operational leases will be reported as fixed assets and financial liabilities in the Group's balance statement. Instead of operational leasing costs, Episurf Medical will report depreciation and interest expenses in the Group's income statement.

Lease liabilities that have previously been classified as operational leases according to IAS 17 will be valued at the present value of the remaining lease payments. Episurf Medical will report a right of use to an amount corresponding to the lease liability. As a result, the transition to IFRS 16 will not have any significant impact on equity. Episurf Medical will apply the practical exemptions regarding reporting payments attributable to short-term leases and leases for assets of a low value as a cost in the income statement. Episurf Medical will not apply IFRS 16 for intangible assets. Non-lease components will be expensed and are not reported as part of

the right of use or the lease liability. The transition to IFRS 16 will have the following preliminary impact on the Group's balance statement at the time of the transition, i.e. 1 January 2019:

Right of use SEK 8m

Financial lease liability SEK 8m

Episurf Medical has identified leases attributable to properties, machines and vehicles. When determining the above amounts, the most significant assessments are attributable to the establishment of the term of the leases. The majority of Episurf Medical's leases include options to either extend or terminate the agreement. When the term of the lease is being established, Episurf Medical takes into consideration all facts and circumstances that provide a financial incentive to utilise an extension option or not to utilise an option to terminate an agreement. Examples of factors that are considered include strategic plans, restructuring programmes, the importance of the underlying asset to Episurf Medical's activities and/or costs attributable to not extending or terminating leases.

Changed accounting principles

In 2018, the following accounting principles have changed:

IFRS 9, Financial Instruments

IFRS 9 deals with classification, recognition and measurement of assets and liabilities. IFRS 9 replaces the parts of IAS 39 that are related to recognition and measurement of financial instruments. IFRS 9 states that financial assets are classified in three measurement categories: amortised cost, fair value through other comprehensive income or fair value through profit or loss. The classification depends on the company's business model and instrument's cash Accounting policies and notes flow characteristics. The transition has had no effect for the company because the group has historically had very low customer losses and the customers have very high credit ratings.

IFRS 15, Revenue from Contracts with Customers

IFRS15 specifies how and when to recognise revenue. According to IFRS 15, revenue is recognised when control of the promised good or service have been transferred to the customer and the customer can use and benefit from the good or service. The standard introduces increased disclosure requirements for reporting of information about the nature, amount, timing and uncertainty of revenue, and the cash flows arising from the company's contracts with customers. IFRS 15 replaces IAS 18 "Revenue" and IAS 11 "Construction Contracts". The Company has assessed that the standard currently does not affect the company. It can be changed in the future when the company change its current contract structure at a higher revenue.

Subsidiaries

Subsidiaries are all companies in which the Group has influence over the investment object, is exposed to or is entitled to variable returns from its involvement in the investment object and can use its influence 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.

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.

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.

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 after December 31, 2017

The Group classifies financial assets and liabilities in accordance with IFRS 9. The classification determines how the financial assets and liabilities are valued and reported. 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;

- Accounts receivables
- Other receivables
- Accrued income
- Cash and cash equivalents

The Group currently does not hold any financial assets that are valued at fair value through profit or loss or at fair value through other comprehensive income.

All of the Group's financial liabilities, consisting of borrowing and accounts payable, are classified as other financial liabilities and are valued at amortised cost.

For the comparative period, IAS 39 was applied for the recognition of financial assets and liabilities. The classification was then made based on the purpose for which the financial asset or liability was acquired. All financial assets are classified as loan receivables and account receivable in the comparative period and are valued at amortised cost.

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. The reported value of accounts receivable, after any write-downs, is assumed to correspond to its fair value, since this item is short-term in nature. Discounting does not occur when the maturity is short.

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. A claim is raised when the Group has performed, and there is a contractual obligation for the counterparty to pay, even if the invoice has not yet been sent. Accounts receivable are recognised in the balance sheet when an invoice has been sent. Debt is recognised when the counterparty has performed, and there is a contractual obligation to provide, even if the invoice has not yet been received. Accounts payable are recognised when the invoice is received.

A financial asset is removed from the balance sheet when the rights in the agreement are realised, expire, or the group loses control over them. The same applies to part of a financial asset. A financial liability is removed from the balance sheet when the obligation in the agreement is fulfilled or otherwise extinguished. The same applies to part of a financial debt.

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 and for the financial assets that are valued at fair value through other comprehensive income. 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.

Financial instruments before January 1, 2018

Classification and valuation of financial instruments before January 1, 2018

Prior to the introduction of IFRS 9 Financial Instruments, January 1, 2018, the Group's holdings of financial assets were classified in the following valuation categories according to IAS 39 Financial Instruments: accounting and valuation: "Financial assets valued at fair value through profit and loss", "Financial assets sold" (valuation at fair value through other comprehensive income) and "Loan receivables and accounts receivable" (valuation at amortized cost). According to IAS 39, financial liabilities were classified as "Financial liabilities at fair value through profit or loss" and "Other financial liabilities" (valuation at amortized cost).

Impairment of financial assets before January 1, 2018

For the comparative period 2017, the Group assessed at the end of each reporting period whether there was objective evidence that impairment requirements existed for a financial asset or group of financial assets. A financial asset or group of financial assets was written down only if there was objective evidence of a write-down requirement as a result of one or more events occurring after the asset was recognised for the first time and that this event has an impact on the estimated future cash flows of the asset that could be reliably estimated.

Cash and cash equivalents

Cash and cash equivalents include cash on hand and at bank and other short-term, highly liquid investments with a maturity of three months or less at the time of purchase.

Share capital

Common shares are classified as equity. Transaction costs that can be directly attributed to the issue of new shares are recognized, 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.

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.

Government grants

Government grants received for research and development projects are recognised in other operating income, over the period necessary to match them with the related costs for which they are intended to compensate.

Interest income

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

Leases

Leases of assets for which substantially all the risks and rewards of ownership are retained by the lessor are classified as operating leases. Payments that are made during the lease term (with a reduction for any incentives from the lessor) are recognised in the income statement on a straight-line basis over the lease term.

At present the Group has a limited number of leases, of which all are operating leases.

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 annual financial statements of the Parent Company are presented in accordance with the Swedish Annual Accounts Act and the Swedish Financial Reporting Board's recommendation RFR 2. Accounting for Legal Entities. The accounting policies applied by the Parent Company differ from those applied by the Group in the cases described below.

IFRS 15 and IFRS 9

According to RFR 2, the parent company applies IFRS 15 in the same manner as described for the Group above. The parent company reports financial instruments as before, based on the acquisition value method. On the other hand, expected credit losses on receivables are reported in accordance with IFRS 9 in the same way as described for the Group above.

Financial assets and liabilities

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

IFRS 16

The new standard IFRS 16 Leases does not affect the parent company because the standard is exempted from application in legal entity. Other new or amended IFRS, including statements adopted so far by the IASB, are not expected to have any material effect on the Parent Company's accounts.

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. In the Parent Company, any provisions are recognised under a separate heading.

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. A group contribution paid by the Parent Company to a subsidiary is recognised during 2015 as a group contribution but from 2016 as an increase in the investment in the subsidiary.

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), 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. 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.

a) 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.

b) Interest

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.

c) Liquidity risk and continued operations

At 31 December 2018, the Group had liquidity of SEK 28.3m (71.3). To assure financing of continued operations, a financing agreement with European Select Growth Opportunities Fund was entered into in February and decided on the Annual General Meeting in April 2018. The agreement provides the company with access to SEK 70m over a 36month period of which SEK 7m was utilised during the second quarter 2018. The company thus has SEK 63m left to use. See more information about the financing agreement below and on the Company's website.

During the fourth quarter, the company carried out a directed share issue to a number of selected investors, including Niles Noblitt (one of the founders of Biomet) and the existing shareholder Rhenman Healthcare Equity L/S. In total, SEK 13.2m before transaction costs was contributed to Episurf.

As the company, in spite of the financing measures outlined above, within the next 12 months has additional financing needs that have not yet been secured, the Board is continuously working on evaluating various financing options to ensure continued operation. It is the Board's assessment that the company has good prospects of securing future financing either with the support of, for example, a new credit facility or through a new share issue.

Future undiscounted cash flows correspond 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 2018 was 81.8 per cent (91.7).

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 2018 the Group had loss carry forwards amounting to SEK 307.4m (248.9) that had not been included in calculation of the deferred tax asset.

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.

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 4.0m (2.5) 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 0.4m (0.2) refer to intra-group sales. Other income mostly consists of currency changes.

Net sales per country

Group	2018	2017
Germany	2.0	1.1
Sweden	0.3	0.2
Other countries in Europe	1.6	1.1
Other countries outside of Europe	--	0.1
Total net sales	4.0	2.5

Other operating income

Group	2018	2017
Other	0.3	0.6
Total other operating income	0.3	0.6

Parent Company	2018	2017
Other	0.0	--
Total other operating income	0.0	--

Note 7 Financial income and expenses

The year's financial income and expenses consist of 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.

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.

Group	2018	2017
	KPMG	KPMG
Audit assignments	0.5	0.4
Other audit assignments	--	--
Tax advice	--	0.0
Other advisory services	0.1	0.0
Total	0.6	0.4
Other auditors	2018	2017
Audit assignments	0.0	0.0
Tax advice	--	--
Other advisory services	--	0.1
Total	0.0	0.1
Parent Company	2018	2017
	KPMG	KPMG
Audit assignments	0.5	0.4
Other audit assignments	--	--
Tax advice	--	0.0
Other advisory services	0.1	0.0
Total	0.6	0.4

Note 9 Personnel costs and remuneration to the Board of Directors, senior executives and other employees

Personnel costs		
Group	2018	2017
Remuneration		
Salary and other remuneration	19.0	24.7
Social security expenses	6.0	6.4
Pension expenses - defined contribution plans	2.1	2.0
Other	0.2	0.2
Total	27.3	33.3
Parent Company	2018	2017
Remuneration		
Salary and other remuneration	8.4	9.3
Social security expenses	3.0	2.7
Pension expenses - defined contribution plans	1.1	1.1
Other	0.1	0.1
Total	12.6	13.2

For salary and remuneration to the CEO, management and Board of Directors, see Note 23.

Average number of employees

	2018		2017	
	Average no. Of employees	Of whom men	Average no. Of employees	Of whom men
Group and Parent Company				
Group	25	13	27	16
Parent company	12	3	13	5

Gender distribution of Board members and other senior executives

	2018		2017	
	Average no. Of employees	Of whom men	Average no. Of employees	Of whom men
Group and Parent Company				
Board members	5	4	6	5
CEO and senior executives	6	3	6	3
Total Group and Parent Company	11	7	12	8

Incentive programmes

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 are 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 one share of series B in the Company during the period from and including 1 June 2021 until and including 31 May 2022 for a price of SEK 7.53. Each warrant of series 2018/2021(A) entitles its holder to subscribe for one share of series B in the Company during the period from and including 1 June 2021 until and including 31 May 2022 for a subscription price of SEK 7.53.

The programme implied that a maximum of 322,000 shares of series B were issued, corresponding to a maximum dilution of approximately 1.0 per cent of the shares and approximately 0.8 per cent of the votes in the Company.

Changes in outstanding stock options	2018
Granted	250,500
Expired	-18,000
Amount at end of year	232,500

Input information	Grant date
Calculation model	Black-Scholes
Share price	6.70
Subscription price	7.53
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

	31 Dec 2018
Total expense recognized during the year, including social security charges	0.1
Debt, end of December, social security charges	0.0

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 are 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 one share of series B in Episurf Medical during the period 1 June 2020 – 31 May 2021 for a price of SEK 8.55, corresponding to 130 per cent of the average volume weighted share price for Episurf Medical's share of series B on Nasdaq Stockholm during the period from and including 15 May 2017 until and including 19 May 2017. Each warrants of series 2017/2020(A) entitles its

holder to subscribe for one share of series B in Episurf Medical during the period 1 June 2020 – 31 May 2021 for a price of SEK 8.55. The programme implies that a maximum of 631.100 shares of series B may be issued, corresponding to a maximum dilution of 2.0 per cent of the share capital and 1.4 per cent of the votes in Episurf Medical. The employee stock options is recorded as a personnel expense in the income statement during the vesting period. The total costs for the employee stock options are expected to amount to SEK 0.7 million during the term of the programme. As per the date of this Annual Report, the company has allotted a total of 471.775 employee stock and 117.400 warrants.

Changes in outstanding stock options	2018	2017
Opening balance	471,775	--
Granted	--	500,225
Expired	-38,950	-28,450
Amount at end of year	432,825	471,775

Input information	Grant date
Calculation model	Black-Scholes
Share price	6.58
Subscription price	8.55
Grant date	2017-05-22
Vesting date	2020-05-31
Expected dividend	--
Risk free interest rate	-0.020
Expected volatility	30%
Fair value per option	0.93

	31 Dec 2018	31 Dec 2017
Total expense recognized during the year, including social security charges	0.1	0.1
Debt, end of December, social security charges	0.0	0.0

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 means that the participants will be allotted a certain number of employee stock options free of charge. Provided that the participant is still employed by Episurf Medical at the exercise of the options, each employee stock option entitles the employee to purchase one B share in the company at a subscription price of SEK 22.80. The employee stock option may be exercise during the period from and including the date falling three years from the date the employee is allotted the employee stock options until and including the date falling four years after the date the employee is allotted the employee stock options. The Programme comprises a maximum of 151.600 employee stock options which can be allotted as follows: (i) maximum 53.200 employee stock options to the CEO. (ii) maximum 40.500 employee stock options to the CFO. (iii) maximum 33.900 employee stock options to the COO. and (iv) maximum 2.000 each in total to twelve other employees of Episurf Medical. As per the date of this Annual Report. Episurf Medical has allotted a total of 96.400 employee stock options as per the following: 40.500 to the CFO; 33.900 to the COO; and 22.000 employee stock options in total to 11 other employees of Episurf Medical.

Changes in outstanding stock options	2018	2017
Opening balance	96,400	149,600
Granted	--	--
Expired	--	-53,200
Amount at end of year	96,400	96,400

Input information	Grant date
Calculation model	Black-Scholes
Share price	15.20
Subscription price	19.70
Grant date	2016-08-18
Vesting date	2019-08-18
Expected dividend	--
Risk free interest rate	-0.020
Expected volatility	30%
Fair value per option	1.55

	31 Dec 2018	31 Dec 2017
Total expense recognized during the year, including social security charges	0.0	0.0
Debt, end of December, social security charges	0.0	0.0

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 bonus is subject to a vesting period of three years and may at the earliest be paid on 18 August 2019 and no later than 18 August 2020. The value of the deferred cash bonus will be calculated as the closing price of Episurf Medical's share listed on Nasdaq Stockholm on the exercise date reduced by SEK 22.80 multiplied by 2.000. The deferred cash bonus will thereby reflect the financial conditions for the group of employees in Episurf Medical which were allotted a maximum of 2.000 employee stock options under the Employee Stock Option Programme. The disbursement of the bonus amount requires that the employee is still employed by Episurf Medical when the bonus is paid out.

Change cash bonus	2018	2017
Opening balance	18,000	22,000
Granted	--	-4,000
Expired	-6,000	--
Amount at end of year	12,000	18,000

Input information	31 December 2018
Calculation model	Black-Scholes
Share price	2.90
Subscription price	19.70
Grant date	2016-08-18
Vesting date	2019-08-18
Expected dividend	--
Risk free interest rate	-0.020
Expected volatility	30%
Fair value per option	1.55

	31 Dec 2018	31 Dec 2017
Total expense recognized during the year including social security charges	-0.0	-0.0
Debt, end of December, including social security charges	-0.0	-0.0

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	2018	2017
Profit before tax	-57.8	-61.1
Income tax calculated at the Group's applicable tax rate, 22%	12.7	13.4
Income that is exempt from taxation	0.0	0.0
Expenses not deductible for tax purposes	-0.2	-0.1
The year's tax loss carryforward not recognised as deferred tax assets	12.5	13.4
Income tax expense	--	0.0

*Tax attributable to previous years

At 31 December 2018 (2017) the Group had loss carry forwards amounting to SEK 307.4m (248.9) that have not been included in calculation of deferred tax.

Parent Company	2018	2017
Profit before tax	-29.7	-29.7
Income tax calculated at the Group's applicable tax rate, 22%	6.5	6.5
Income that is exempt from taxation	--	0.0
Expenses not deductible for tax purposes	-0.1	-0.1
The year's tax loss carryforward not recognised as deferred tax assets	6.4	6.5
Income tax expense	--	--

At 31 December 2018 (2017) the Parent Company had loss carry forwards amounting to SEK 202.9m (173.3) that have not been included in calculation of deferred tax.

Note 11 Intangible assets

Group		
Patents	31 Dec 2018	31 Dec 2017
Opening cost	20.5	16.7
Purchases	5.4	3.7
Closing accumulated cost	25.9	20.5
Opening depreciation	-11.2	-8.5
The year's depreciation	-3.0	-2.8
Closing accumulated depreciation	-14.2	-11.2
Closing carrying amount	11.6	9.3
Development expenses		
Closing cost	8.6	4.9
The year's capitalisation	4.7	3.7
Closing accumulated cost	13.3	8.6
Opening depreciation	-1.8	-0.6
The year's depreciation	-2.0	-1.3
Closing accumulated depreciation	-3.9	-1.8
Closing carrying amount	9.5	6.8
Closing carrying amount, patents and development expenses	21.1	16.0

Parent Company		
Development expenses	31 Dec 2018	31 Dec 2017
Opening cost	8.6	4.9
The year's capitalisation	4.7	3.7
Closing accumulated cost	13.3	8.6
Opening depreciation	-1.8	-0.6
The year's depreciation	-2.0	-1.3
Closing accumulated depreciation	-3.9	-1.8
Closing carrying amount, development expenses	9.5	6.8

Note 12 Property, plant and equipment

Group	31 Dec 2018	31 Dec 2017
Opening cost	1.0	1.0
Purchases	--	0.0
Closing accumulated cost	1.0	1.0
Opening depreciation	-0.7	-0.6
The year's depreciation	-0.1	-0.2
Closing accumulated depreciation	-0.9	-0.7
Closing carrying amount	0.1	0.2
Parent Company	31 Dec 2018	31 Dec 2017
Opening cost	0.7	0.7
Purchases	--	--
Closing accumulated cost	0.7	0.7
Opening depreciation	-0.6	-0.5
The year's depreciation	-0.1	-0.1
Closing accumulated depreciation	-0.7	-0.6
Closing carrying amount	0.0	0.1

Note 13 Shares in group companies

Parent Company	31 Dec 2018	31 Dec 2017
Opening cost	78.3	46.2
Investment	0.0	--
Capital infusion	28.5	32.1
Closing carrying amount	106.8	78.3

Name	Corporate identification no.	Domicile	% of capital	No. Of shares	Equity at 31 Dec 2018
Episurf IP-Management AB	556921-7747	Stockholm, Sweden	100%	10 000	0.3
Episurf Operation AB	556921-7739	Stockholm, Sweden	100%	10 000	0.3
Episurf Europe AB	556921-7721	Stockholm, Sweden	100%	10 000	0.6
Episurf UK Ltd	9 548 146	Lincoln, UK	100%	1	-1.6
Episurf DE GmbH	HRB 218113	München, Germany	100%		-0.7
Episurf Medical Inc	34-408080832	Delaware, USA	100%	1 000	0.0
Episurf India Private Limited	U74999DL2018FTC342052	New Delhi, India	100%	100 000	--

During 2018, the company acquired 100% of Episurf Medical Inc and Episurf India Private Limited. No other changes have occurred.

Note 14 Related party transactions

The Parent Company's holdings of shares and participations in subsidiaries are specified in note 13.

Parent Company	31 Dec 2018	31 Dec 2017
Non-current non-interest-bearing receivables	24.0	20.0
Total related party transactions	24.0	20.0

The change in 2018 refers to the net of payments including shareholders contributions to the company's subsidiaries.

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 0.9m (1.0) The company has written down SEK 0.1m (-) of the company's trade receivables.

Group	31 Dec 2018	31 Dec 2017
Trade receivables	0.9	1.0
Less: provisions for doubtful debts	-0.1	--
Trade receivables, net	0.8	1.0

Note 16 Inventories

Group	31 Dec 2018	31 Dec 2017
Cost of inventories		
Finished goods	1.5	1.7
Total inventories before impairment	1.5	1.7

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

Note 17 Deferred expenses and accrued income

Group	31 Dec 2018	31 Dec 2017
Prepaid rents	0.4	0.4
Accrued income	0.1	--
Other items	0.9	1.4
Total deferred expenses and accrued income	1.3	1.8

Parent Company	31 Dec 2018	31 Dec 2017
Prepaid rents	0.4	0.4
Other items	0.2	0.4
Total deferred expenses and accrued income	0.6	0.8

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
Balance at 31 December 2017	30.549.495	9.172.606
Issue In-kind. for conversion of debt	1.081.674	324.777
Directed share issue*		986.898
Balance at 31 December 2018	31.631.169	10.484.281

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 31.631.169 shares, 5.221.662 were class A shares and 26.409.507 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:

SEKm	
Share premium reserve	344.9
Accumulated deficit	-180.9
Loss for the year	-29.7
Total	134.3

The Board proposes that the earnings be appropriated so that SEK 134.3m is carried forward to new account.

Note 19 Current interest-bearing liabilities

Group and Parent Company	31 Dec 2018	31 Dec 2017
Received cash from issue of convertible debentures	7.0	--
Transaction costs	-0.3	--
Net proceeds	6.7	--
Amount classified as equity	-0.5	--
Conversion convertible	-4.1	--
Accrued interest	0.6	--
Reported value as of December 31, 2018	2.8	--

Other financial assets and liabilities in the balance sheet are reported as acquisition value, which is judged to be a good approximation to the fair value of the items.

Note 20 Other liabilities

Group	31 Dec 2018	31 Dec 2017
Personnel-related liabilities	1.1	0.8
Other	0.4	0.6
Total other liabilities	1.6	1.4
Parent Company	31 Dec 2018	31 Dec 2017
Personnel-related liabilities	0.5	0.4
Other	0.1	0.2
Total other liabilities	0.7	0.6

Note 21 Accrued expenses and deferred income

Group	31 Dec 2018	31 Dec 2017
Accrued personnel-related expenses	2.1	2.5
Accrued Board fees	0.4	0.5
Accrued consulting fees	1.5	0.8
Total accrued expenses and deferred income	4.0	3.8
Parent company	31 Dec 2018	31 Dec 2017
Accrued personnel-related expenses	1.6	1.5
Accrued Board fees	0.4	0.5
Accrued consulting fees	1.3	0.6
Total accrued expenses and deferred income	3.3	2.5

Note 22 Future lease payments

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

Group and Parent Company	31 Dec 2018	31 Dec 2017
Within one year	1.3	1.6
Between one and five years	0.1	1.2
Later than five years	--	0.0
Total obligations	1.4	2.9

Obligations under operating leases The Group leases premises, cars and a few items of office equipment under cancellable operating leases. The notice periods for cancellation of these leases vary between 12 months and 3 years.

Note 23 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 period of SEK 0.6m (0.7).

As a technical measure in order to meet European Select Growth Opportunities Funds demand for immediate access to its shares, certain shareholders, during a transitional period, lend shares to the issuing agent engaged for this agreement. The Chairman and Members of the board's fees were agreed by the AGM and is shown below.

The Chairman receive SEK 0.4m. Wilder Fulford and Laura Shunk receive remuneration of SEK 0.2m. Leif Ryd and Christian Krüeger receive remuneration of SEK 0.1m respectively. In total, the board fees amount to SEK 1.0m (1.1).

Variable remuneration for the financial years 2018 and 2017 is an expensed bonus, to be paid in 2019 and 2018.

The Group has only defined contribution pension plans. The pension expense refers to the expense that has affected profit for the year.

2018	Salary/fees	Variable remuneration	Other benefits	Pension expense	Other remuneration	Total
Board Chairman, Dennis Stripe	0.4					0.4
Board member, Laura Shunk	0.2					0.2
Board member, Leif Ryd	0.1				0.6	0.7
Board member, Christian Krüeger	0.1					0.1
Board member, Wilder Fulford	0.2					0.2
CEO Pål Ryfors	1.5	0.3	0.1	0.3		2.3
Other senior executives	4.4	0.3	0.1	0.7		5.3
Total	6.9	0.6	0.2	1.0	0.6	9.2

2017	Salary/fees	Variable remuneration	Other benefits	Pension expense	Other remuneration	Total
Board Chairman, Dennis Stripe	0.4				0.3	0.7
Board member, Laura Shunk	0.2					0.2
Board member, Leif Ryd	0.1				0.7	0.8
Board member, Saeid Esmaeilzadeh	0.1					0.1
Board member, Christian Krüeger	0.1					0.1
Board member, Wilder Fulford	0.2					0.2
CEO Rosemary Cunningham Thomas	3.2					3.2
CEO Pål Ryfors	1.4	0.3	0.0	0.3		2.1
Other senior executives	3.5	0.3	0.0	0.4		4.2
Total	9.1	0.6	0.1	0.7	0.9	11.4

Bonus

A bonus for 2018 will be paid to all of the company's employees based on the degree of goal fulfillment for annual goal for 2018.

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 24 Significant events after the end of the financial year

- » Episurf Medical announced the start of a comparative investigator-initiated clinical study performed at the Julius Wolff Institute, Charité University Hospital, Berlin
- » New Australian and Canadian patent approvals for Episurf Medical
- » Clinical results for Episealer® was presented at a German clinical congress in February
- » Episurf Medical reached milestone of 500 implants
- » Progress for Episurf medical in initiation of Episealer® Knee IDE study

Note 25 Pledged assets and contingent liabilities

Group and parent company	31 Dec 2018	31 Dec 2017
Rent deposit	0.3	0.3
Total pledged assets and contingent liabilities	0.3	0.3

The group and parent company's surety undertakings and contingent liabilities amounted to 300.000 SEK (300.000) and consists of a rent deposit.

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 7, 2019. 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 April 8, 2019.

Stockholm, 7 March 2019

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 7 March 2019
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

Opinions

We have audited the annual accounts and consolidated accounts of Episurf Medical AB (publ) for the year 2018. The annual accounts and consolidated accounts of the company are included on pages 38-95 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 2018 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 2018 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 49-56.

A corporate governance statement has been prepared. The statutory administration report and the corporate governance statement are consistent with the other parts of the annual accounts and consolidated accounts, and the corporate governance statement is in accordance with the Annual Accounts Act.

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 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.

Material uncertainty related to going concern

Without qualifying our opinion above, we bring to your attention the information on page 42 of the administration report which notes that the company will need additional financing and that the Board is evaluating various alternatives. No additional financing has been finalized as of the date of this report. This condition indicates the existence of a material uncertainty as to the company's ability to continue as a going concern.

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. In addition to the emphasis of matter regarding going concern, the following matter has been determined to be a key audit matter to be communicated in our audit report.

Intangible assets

See note 11 and accounting principles on pages 75-76 in the annual account and consolidated accounts for detailed information and description of the matter.

Description of key audit matter

The consolidated carrying value at 31 December 2018 for capitalized development costs and patents totaled 9.5 MSEK and 11.6 MSEK, respectively. These intangible fixed assets comprise approximately 38.5 % of the consolidated total assets and are subject to impairment tests.

The impairment tests 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 tests related to intangible fixed assets 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 intangible assets.

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 examined the sensitivity analysis prepared by group management to evaluate how reasonable changes in the assumptions may impact the valuation.

Other Information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 3-37. The Board of Directors and the Managing Director 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.

Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director 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 Managing Director 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 Managing Director 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 Managing Director intend to liquidate the company, to cease operations, or has no realistic alternative but to do so.

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 Managing Director.
- Conclude on the appropriateness of the Board of Directors' and the Managing Director'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, 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

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 Managing Director of Episurf Medical AB (publ) for the year 2018 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 Managing Director be discharged from liability for the financial year.

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.

Responsibilities of the Board of Directors and the Managing Director

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 Managing Director 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.

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 Managing Director 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 .

KPMG AB, Box 382, 101 27, Stockholm, was appointed auditor of Episurf Medical AB (publ) by the general meeting of the shareholders on the 9 April 2018. KPMG AB or auditors operating at KPMG AB have been the company's auditor since 2015.

Stockholm 7 March 2019

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

Arthritis:	See Osteoarthritis.
Arthroscopy:	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).
Cartilage:	Shock absorbing and friction reducing tissue. This tissue that covers the end of bones and allows movement with low friction.
Cartilage defect of grade III (ICRS scale):	Lesion through the cartilage, exposing the bone.
Cartilage defect of grade IV (ICRS scale):	Defect extending down to >50% of the cartilage depth.
CE marking:	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.
Clinical results:	Outcome from clinical treatment of humans, where parameters such as efficacy and safety are evaluated.
Cobalt chrome:	A metal alloy mainly consisting of cobalt and chromium, commonly occurring in metal alloys used in knee prostheses.
Debridement:	Removal of damaged tissue.
Degenerative origin:	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.
FDA:	US Food and Drug Administration.
Focal cartilage defect:	A cartilage defect in a well-defined area.
Femoral condyles:	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).
Gross order intake:	Gross order intake represents the aggregated value of Episealer® orders received and approved by responsible surgeon during the relevant period.
Hydroxyapatite:	A mineral that is the major component of human bone tissue and the main mineral of dental enamel and dentin.
Invasive treatment alternative:	Treatments that require a surgical procedure.
Micro fracturing:	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.
Mosaicplasty:	A biological surgical technique for treatment of cartilage and underlying bone defects where cylindrical bone and cartilage plugs are harvested from less weight-bearing surfaces of the knee joint and inserted into the damaged area.
MRI:	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.

OA:	See osteoarthritis.
Order backlog:	Order backlog represents all orders that have been booked but where no revenue has been recognized.
Orthopaedics:	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.
Osteoarthritis:	A type of joint disease that is characterised by loss of joint function with varying destruction of joint cartilage and the underlying bone.
Osteochondral defect:	Cartilage and underlying bone defect.
Prosthesis:	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,
Reimbursement:	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.
TKA:	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).
Traumatic damage:	Damage caused by an outside force, such as fall injuries.
UKA:	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, 8 April 2019, at 10:00 p.m. at Episurf, Karlavägen 60, 114 49 Stockholm.

Notice of the AGM will be made via the company's website www.episurf.com and through an announcement in the Official Gazette (Post- och Inrikes Tidningar), where the date and agenda of the AGM are presented. An announcement that notice has been given will be published in Dagens Industri.

The nominating committee ahead of the AGM consists of Dennis Stripe (Chairman of Episurf Medical AB). Saeid Esmaeilzadeh (representing Serendipity Ixora AB). Peter Ragnarsson (representing LMK Stiftelsen) and Leif Ryd (representing Gile Medicinkonsult AB.) The Chairman of the Nomination Committee is Saeid Esmaeilzadeh.

Participation and registration

Shareholders who wish to participate in the AGM must be recorded in the share register maintained by Euroclear Sweden AB by Tuesday, 2 April 2019, and must register to participate by Tuesday, 2 April 2019.

Registration can be sent by mail to: Episurf Medical AB, Karlavägen 60, 114 49, Stockholm or on the website www.episurf.com.

To register, the shareholders must provide their name, address and telephone number, personal or corporate identification number, registered number of shares and number of assistants. For shareholders who will be represented by a proxy, the registration must include a form of proxy and other proof of authorisation. In order to participate in the AGM, shareholders whose shares are registered in the name of a trustee through a bank's notary department or other trustee must request that the shares be temporarily recorded in their own names in the share register held by Euroclear by Tuesday, 2 April 2019. The shareholder must notify the trustee of this in good time prior to this date.

Financial calendar

Interim Report January – March 2019	26 April 2019
Interim report January–June 2019	19 July 2019
Interim report January–September 2019	25 October 2019
Year-end report for 2019	7 February 2020

IR-contact



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