





Annual report 2015



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- » The first Episealer® surgery in a human was performed in December 2012. At the end of 2015, a total of 73 surgeries had been performed throughout Europe and the results have been very successful. In January 2016, the 100th account was connected to µiFidelity®.
- » 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.

Episurf Medical

- a unique solution for every patient

Episurf Medical was founded in 2009 on a commitment to offering people with painful joint injuries a more active and healthy life through customised treatment alternatives. We put the patient in the centre of the diagnosis and design of implants and surgical instruments. By combining advanced 3D imaging technology with the latest manufacturing technology, 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 system for patient-specific design and surgical pre-planning

The scalable µiFidelity® system has been developed for diagnostics, surgical pre-planning and cost-effective patient customisation. In a first step, the company's main focus is 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 implants on the market.

- » Episealer® Condyle Solo for the treatment of localised cartilage and underlying bone defects in the knee joint.
- » Episealer® Trochlea Solo for the treatment of localised cartilage and underlying bone defects in the area behind the patella.
- » Episealer® Femoral Twin for the treatment of localised cartilage and underlying bone defects both in the knee joint and in the area behind the patella.



Episealer® Condyle Solo



Episealer® Trochlea Solo



Episealer® Femoral Twin



Drill guides

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 procedures.

Around 80 patents and patent applications

The technology that creates patient-specific implants and instruments is supported by a strong patent portfolio with approximately 80 patents and patent applications in the areas of image handling, patient-specific implant systems, patient-specific surgical techniques, patient-specific instrumentation and manufacturing for all of the body's joints.



- » The first surgeries with the Episealer® Condyle Solo implant in the UK are performed with successful results.
- » A Belgian patient with a 10-year history of knee problems and a number of unsuccessful interventions is symptom-free after receiving an Episurf implant.



- » A patent is granted in the USA relating to the company's surgical kit, consisting of the patient-specific guide, Epiguide®, and related surgical tools, Epikit.
- » Direct sales are started in Germany and the UK.
- » Rosemary Cunningham Thomas is appointed as the new CEO.



- » CE mark is received for the company's third implant, Episealer® Femoral Twin.
- » The Board of Directors decides on a rights issue of up to approximately SEK 120 million with preferential rights for the company's shareholders and proposes a private placement directed to Episurf Medical's new CFO. An extraordinary general meeting on August 21 resolves on the rights issue.
- » 97.8 per cent of the new shares are subscribed by the shareholders and the company raises SEK 120 million before issue expenses.



- » A Clinical Advisory Board consisting of European Key Opinion Leaders is appointed.
- » Epiguide® MOS receives CE mark.
- » Episurf's first surgery in Switzerland is successfully completed.
- » The first two surgeries with Episealer® Femoral Twin are performed in Germany with satisfactory results.

Key ratios	2015	2014	Total
Number of surgeries performed	51	13	73
Number of new connected users	61	14	100¹
Number of new CE-marked products	2	1	42
Number of new patents	11	3	50 ³

- 1) Reached in January.
- 2) Five in January 2016.
- 3) The remainder of up to 80 are patent applications.

Milestones in 2015, completed



After year end

- » CE mark is received for Epioscopy™ Damage Assessment Tool.
- » A German website is launched at the same time that marketing activities are intensified in the region.
- » Episurf reaches 100 accounts, approved and connected to the µiFidelity® platform.
- » The scientific abstract "On the attachment of cartilage to HA: Signs of 'chondrointegration' Studies on the Episealer® mini-prosthesis in the sheep knee," is granted a poster presentation at the orthopaedic conference ESSKA.
- » Episealer® is approved by Spire Hospital in the UK for private insurance patients.

[1]

The perfect marriage of advanced digital imaging techniques and precision engineered bespoke implant technology

Rosemary, you have now been the CEO of Episurf Medical since June 2015. Tell us about your first 10 months in the company

It was clear from day one that Episurf Medical's patient specific technology platform offered surgeons and patients an intelligent yet simple solution for the treatment of cartilage lesions. This was coupled with a growing market demand for clinically effective treatments for the middle age patient. Upon meeting the Episurf Medical team, it was evident that we could build the company's early research and develop-

of execution and individual accountability were also a priority. This continues to improve.

Half the challenge was to ensure that the company had the right talent in key positions to enable this transition. Personnel changes were made to create the optimum structure. Most early stage med tech companies outside of Sweden are not publically listed, so this was an added, albeit, interesting challenge.

There was an immediate need to establish a sales process and early clinical marketing support tools to assist early sales efforts. We then developed a set of business metrics prospective CPL data collection to include all new customers, implementing a new CRM system and developing a pipeline of regular news flows. On the marketing side, we developed a go-to market strategy and the Episurf value proposition which was complemented by focused branding and advertising activities. On the clinical side, Episurf has a developing strategy focused on abstract development, Episealer® podium presentations, surgeon training, digital CPL data collection and health economic studies. Most importantly, the new share issue provided the working capital to fuel our growth plans.

It's been an exhilarating 10 months. Through company-wide teamwork and collaboration, an excellent Episurf esprit de corps has been developed along with a strategic growth plan. We now have a strong foundation in place to support our expansion activities and will continue to evolve and develop over the coming years.

"We now have a strong foundation in place to support our expansion activities"

ment achievements into a commercial success story. This foundation became the springboard from which to develop a compelling company vision, a focused growth strategy and commercial execution plan.

We had to rapidly transition from an internally focused start-up to an early-stage medical technology company focused on the market and customers, whilst pivoting into a globally-focused, performance-driven organisation. Speed

to ensure we could understand and measure our activities and performance.

Once the basic business intelligence processes were established, a short-term executive agenda to fuel our long-term growth strategy was developed. This included establishing a clinical advisory board comprised of European orthopaedic key opinion leaders, hiring sector-specific top sales professionals in the key European markets, expanding our

And based on the current progress, what is the focus for the coming year?

In line with our quality management goals, each area of the business - Sales and Marketing, Finance, Operations and Development, QA/RA, Clinical Affairs and HR – is working to support and accelerate the strong sales trends that we are experiencing in early 2016.

[2]

Early in 2016, you announced that you had reached the target of connecting 100 accounts to µiFidelity®, what will this mean for the company's sales?

The 100 connected accounts will function as a pipeline for new implant business whilst ensuring account productivity and repeat revenue.

We also know there is a lead time between a surgeon identifying a patient, agreeing to do an Episealer® procedure and the completed implant surgery. The lead time can be extended due to delayed MRI access. In the second half of 2015, we focused on starting up new accounts, complete with MRI the protocol installed and validated to overcome potential bottlenecks. The main focus for 2016 is to get these accounts productive. But an average lead time from identifying a prospective Episealer® patient to the first surgery is yet to be established.

You have installed your IT-system µiFidelity® at more than one hundred accounts. How do you see this platform being developed to provide additional qualified services to the clinics?

We believe µiFidelity® can develop into a specialised orthopaedic IT platform for doctors and patients. It currently has three modules and is used for the processing of MR images, designing and manufacturing.

We are thinking about building out the following services on $\mu i Fidelity^{\text{\scriptsize @}}:$

- » Professional training and education,
- » A post op rehab program for patients,
- » Post-surgical patient data collection,
- » An online surgical forum for Episealer® users,
- » Providing a data base of clinical information for surgeons and patient education,
- » Providing inbound and outbound marketing content,

- » Order point for consumer who want an Epioscopy $^{\text{TM}}$ report, and
- » Predictive analysis about cartilage defects.

Our ambition is for the µiFidelity® platform to become the central information repository for Episurf and all external stakeholders – surgeons, suppliers, prospective and post op Episealer® patients and healthcare payors. We believe building out µiFidelity will give us a unique competitive advantage whilst providing a platform to have an ongoing conversation with our customers and the broader market.

You have reported very positive outcome from a patient prospective. What has the reaction been from the doctors?

Yes, the direct patient feedback is very exciting. We have two recent examples of positive patient outcomes at the three-year mark. One completed the Vasaloppet 90-kilometre cross country ski race, and another is a full time PE teacher who does his job without problems.

Based on early experience and solid clinical outcomes, our high-volume surgeons believe the Episealer® can be expected to provide significant improvement in clinical symptoms at least over a five-year period. They also find the procedure simple and efficient, taking an average of 30 minutes. And most importantly, they are pleased to have a new clinical treatment option to address the sizable treatment gap that exists between biological interventions and partial or full knee prosthesis procedures.

Medicine today is heavily geared towards an evidence basis. What, in your opinion, would be the least "evidence" in terms of follow-up, case numbers, etc., to motivate use of the Episealer®?

Episurf actively collects pre-surgical demographics, lesion etiology, VAS, KOOS and Eq5D scores and prospective



Rosemary Cunningham Thomas, President and CEO Episurf Medical.

outcome data at 3, 6, 12 and 24 months for all Episealer® implants. We also document lesion size, location and implant positioning during surgery via high resolution photos. Our patient numbers are increasing quickly at the key milestones of one, two and three years.

Growing surgical acceptance is evidenced by the fact that 56 per cent of our surgeons have already performed their second Episealer® surgery and 44 per cent have performed their third surgery using an Episealer®. Also, Episurf Medical

has 0 surgery revisions to date. Four patients have passed three years, 11 patients have passed two years and 36 patients have passed one year since the surgery date.

A range of between 100–200 cases and 2–3 years of follow-up is what most clinicians think is acceptable. As a result, our growing evidence base will enable us to accelerate surgical adoption.

We believe there is a strengthening correlation between the pre-surgical assessment provided by the Epioscopy™ damage-marking process combined with our proprietary Episealer® implant design and the corresponding zero revision rate. Direct surgeon feedback tells us that use of the Epioscopy™ damage-marking report offers a form a pre-surgical quality control that contributes to appropriate patient selection and we believe this will be borne out as more Episealer® patients reach yearly milestones.

Lastly, our prospective patient follow up data continues to show improvement in pain, mobility and general wellbeing scores.

The Episealer® instrumentation is also customised, and designed to provide precision and ease of use. In your opinion, are the instruments successful in this regard and how important would this be as a selling argument?

Market feedback from our growing user base and clinical data indicates that we have solved the technical shortcomings of early re-surfacing technologies. Episurf's proprietary features, including the pre-surgical assessment of subchondral bone quality and opposing tibial cartilage, ensure that the Episealer® is used for the correct clinical indication. The patient-specific design including that the instrumentation delivers a custom fit which in turn ensures correct implant positioning. The one-piece implant design and proprietary HA and titanium coating ensure bone fixation. In particular, we believe the Epiguide® is a key reason why we have no revisions to date and it is therefore central to the sales message.

What's your market focus right now?

We will expand our sales efforts by strengthening our direct sales and marketing activity in the lead European markets for Episurf - Germany and the UK. We have employed experienced orthopaedic sales professionals who have extensive knee surgeon networks in key markets. This approach will help to decrease the time it takes for a new sales person to become productive. We continue to gain new customers across all markets - Germany, the UK, Benelux, the Nordics. To support sales efforts, we are actively developing clinical marketing tools and country-specific reimbursement plans.

We are seeing early reimbursement success in the private health sector. Episealer®'s procedural simplicity and shorter patient recovery times deliver value for this type of payor group.

The number of knee prostheses is increasing dramatically in Europe and the US. How do you see the Episealer® resurfacing technology impacting this situation?

We know that the treatment gap is found in management of articular cartilage defects in patients where biological options are either too expensive (as in many countries) or are likely to have a low success rate – such as in the biologically older patient, probably meaning over age 40. Knee arthroplasty, relining an isolated compartment or relining the entire knee remain significant steps and require a certain level of intrusive symptoms to justify.

Episurf's precise and accurate reconstruction of an individual's anatomy and patient-specific design finally gives surgeons a simple and clinically effective tool to address the sizable treatment gap that exists between biologic interventions and partial or full knee prosthesis procedures.

You are now actively selling the product in parts of Europe. What are your learnings with respect to changing the logistic requirements for ordering and receiving a patient-specific product?

As the business scales, we constantly assess our internal processes to improve efficiency and customer service levels whilst working closely with the supply chain. For example, we completed a µiFidelity® upgrade to ensure the seamless upload of MRI images. We also are considering methods to reduce the design time from receipt of initial MR images to finished goods. To service the growing demand for our products in a timely fashion, we'll be assessing if and when it would be feasible to do in-house manufacturing.

Why have you chosen to go with your own sales force rather than using distributors in northern Europe, and what will be your strategy when you enter into new markets?

Episurf's patient-specific implant technology for focal cartilage lesions is a highly innovative technology that is not appropriate for a distribution model. We are selling a new treatment option and most distribution models work on high turnover of low to mid-value mature products.

Our direct sales activity in Q3/Q4 2015 enabled Episurf to finish the year with solid trends in the number of both new accounts and implants. These are also evidenced by our growing pipeline and order book.

We have established a growing European presence amongst the key cartilage repair surgeons through our direct sales strategy and will work with these surgeons to educate other surgeons. A European distributor would simply not have the time, scope or financial incentive to achieve this. On a final point, at this stage, it is important that we ensure a level of quality control around surgical users and their technique. A direct sales strategy means that we know every surgeon and every Episealer® patient result to date.

The USA is the largest single market for this type of product. So far, in early 2016, what's been done with respect to the US market?

The USA is the world's largest orthopaedic device market with the highest number of knee arthroscopies, 3.7 million, 1.1 million knee replacements annually and up to 6 million people visiting their doctors each year due to articular cartilage damage in the knee.

The US healthcare ecosystem is acutely aware that the US population is getting older, sicker, fatter and more sedentary. The demographic explosion of people with serious knee problems is growing, resulting in catastrophic financial strains on the entire healthcare economy.

A critical component for driving down spiralling knee surgery costs will be the delivery of early treatment options with short rehab times. Importantly, the US healthcare market is consumer-driven, with individuals financing their own healthcare, or contributing to private insurance policies. As a result, patients as 'healthcare consumers' are more open to paying for innovative procedures that deliver results, and enable them to work and enjoy active lifestyles. Episealer® can put US patients in the driver's seat with respect to their own health outcomes. Additionally, the healthcare payors are competing against each other and see the benefit of early, minimally invasive surgical procedures that reduce the cost of health through improved health outcomes.

The USA is a complex, diverse and fragmented market with regard to regulatory and reimbursement pathways. In line with previous communication, Episurf has appointed two specialist consultancies to work with us on mapping out the route to FDA approval and product reimbursement. At project completion, we'll know what will be required for US market entry in terms of timing and costs.

We are also working with specialist advisors to assess commercial strategies. To be effective in the US market, Episurf will require the right geographical sales and marketing coverage and access to established clinical networks. This is likely to be achieved via a partner.

What is the long-term strategy for Episurf, and how will you achieve it?

Our strategic objective is for patient-specific implants to become the standard of care for early focal cartilage defects, whereby Episurf implants deliver superior performance that offer improved clinical and health economic benefits for clinicians, patients and payors compared to off-the-shelf implants.

"Our focus is clear – we must deliver commercial results"

Product performance, increasing patient demand and consistent clinical results will move the Episurf technology into the mainstream. We anticipate that increasing the rate of surgical adoption to drive volumes in Europe followed by a successful launch into the US market will increase gross margins. Our focus is clear – we must deliver commercial results to create sustained shareholder value.

Tell us a little bit about yourself. Who is Rosemary Cunningham Thomas and what attracted you to Episurf Medical?

When I evaluated the Episurf CEO opportunity and core technology platform, I immediately recognised its significant and enormous potential. It has all the hallmarks of what is required to become a highly successful medical device – a true technology innovation, protected by strong IP that is solving a problem for which there is no current treatment option. The real hook for me was the proprietary IT platform, µiFidelity®, which not only assesses cartilage damage but then creates the patient-specific anatomical model.

This is the perfect marriage of using advanced digital imaging techniques and fusion software combined with a precision engineered bespoke IP protected implant technology – a killer combination! It's my view that the µiFidelity® IT platform is hugely scalable for other applications and rev-

enue generating opportunities. And the growing incidence and prevalence of early cartilage damage in younger to middle age prospective patients mean that Episurf is in the right place at the right time with the right treatment option.

On a personal note, I am an Anglo/American who was born, raised and educated in the USA. My natural American dynamism works in harmony with a pragmatic British sensibility and a creative European flair. As a business leader, I am highly focused, forward-thinking, performance-driven,

determined, competitive and extremely resilient in the face of challenges.

Years of travel have helped me to develop sophisticated diplomacy skills and a global outlook. It's been said that I lead from the front whilst working in a supportive and collaborative manner with peers and subordinates to ensure their success and productivity. I value working in a creative, innovation-led environment. My temperament is optimistic and I have a lighthearted side that keeps me grounded. Having a sense of fun and joy in one's chosen work is important for peace of mind and company morale.

It's crucial to stay close to the customers, current and future shareholders and key suppliers. So, I spend significant time in market. A company's CEO must not only be a strategist but also a brand ambassador and skilled operational executive; these roles play to my strengths.

I am deeply passionate about innovative healthcare technology and its ability to improve a patient's life. The patient's experience is always at the front of my mind. My entire professional career has been spent enabling clinicians and med tech providers to achieve improved patient outcomes via collaboration and partnerships. Episurf and I are a great fit because I am leveraging my lengthy sector experience to support our growth journey.

London, United Kingdom in April 2016

Rosemary Cunningham Thomas, President and CEO Episurf Medical.

History

- » Episurf Medical's business started as an internal project at Diamorph AB with the aim of developing implants and related surgical instruments to enable the repair of cartilage damage in human knee joints.
- » The first patent application was filed.
- » Diamorph Medtech AB changed name to Episurf Medical AB, which was then spun off from Diamorph AB and listed on Aktietorget.
- **»** A new share issue provided the company with proceeds of SEK 9 million.
- Suppliers and development partners were identified and contracted.
- » An initial pre-clinical validation study (1-year study) on sheep was undertaken.
- The company's first clinical trial was initiated with the aim of evaluating safety and performance of the personalised implant Episealer® Condyle Solo for treatment of cartilage lesions in the knee joint.
- >> The first patent was obtained.
- **»** The first surgery in a human was conducted within the scope of the clinical trial.

- » Good clinical results from the surgeries performed to date with the personalised implant Episealer® Condyle Solo within the scope of the controlled product launch (CPL).
- » CE mark approval was obtained for the company's second commercial product, Episealer® Trochlea Solo, and the company's second CPL could begin.
- » Additional clinics were connected to the company's ongoing clinical trial with Episealer® Condyle Solo with the aim of widening patient recruitment and accelerating the pace of the study.
- » Building of an in-house European marketing and sales organisation began and a direct marketing initiative was started in the Benelux countries.
- » Episurf Medical was listed on the Nasdaq Stockholm's main market.



- » Pre-clinical pilot studies were carried out on sheep with the aim of evaluating the functionality and stability of the implant.
- » Diamorph Medtech AB was formed as a subsidiary of Diamorph AB.
- » Positive results that strengthened and confirmed earlier indications were presented from the completed pre-clinical 1-year study.
- » The development of µiFidelity® began. µiFidelity® enables order management, design and manufacture of personalised implants and surgical tools.
- **»** A new share issue provided the company with proceeds of around SEK 49 million.
- » Episurf Medical AB was listed on Nasdaq OMX First North.



» Two preferential rights issues and a new share issue with pre-emptive rights for existing shareholders were carried out and provided the company with total proceeds of around SEK 75 million before issue expenses.

pain relief in line with expectations.

- » Episurf Medical's first commercial product, Episealer* Condyle Solo, was approved for CE marking and the company's first controlled product launch (CPL) could be started together with selected surgeons from clinics in Northern Europe.
- The company was granted Vinnova financing of SEK 4.2 million.



- » Patents were obtained in the US for the company's surgical kit, i.e. the patient-specific drill guide, Epiguide®, and the related surgical toolkit, Epikit.
- » Direct sales in Germany and the UK were started.
- » CE mark was obtained for the company's third implant Episealer® Femoral Twin and for Epiguide® MOS.
- » A new share issue provided the company with proceeds of SEK 120 million before issue expenses.
- » A clinical Advisory Board consisting of European Key Opinion Leaders was appointed.
- The two first surgeries with Episealer® Femoral Twin were performed in Germany with the desired results.
- » IISO13485:2012 Annex II certification was obtained, which permits CE-marking of own products.





Episurf has performed surgeries in 11 European countries, all with successful results.

+



Lena

Swedish patient, 59 years

Woman

Profession: Sedentary office job

Treatment prior to Episealer®: Keyhole surgery to shave the meniscus

Lena walks or rides her bicycle 4 kilometres to work every day. A few times a week she exercises at a gym. It was while running on the treadmill at the gym that she first felt an unusual pain in her knee.

"The hole was repaired with a kind of plug that was made exclusively to fit my injury. The operation went very quickly and I was able to go home the same day.

"If I hadn't had that operation the hole in the cartilage might have become even bigger and later on I might have had to replace the entire knee joint. Now I hope that won't be necessary."

Source: Elsa Maréchal, Thanks to the new method, I don't have to replace my knee!, Hemmets, June 2, 2015.

Post-operation:

- » Back at work after 14 days
- » After 6 weeks, walks without crutches
- » After 3 months, no pain at all and full function
- » After 12 months, no pain at all and full function



Virginie

Belgian patient, 38 years

Profession: nurse

Treatment prior to Episealer®: Five procedures including arthroscopy, mosaicplasty and ACL reconstruction

"I suffered from constant pain and swelling that was triggered by even the slightest activity. I was always tired, slept poorly and had no energy. I underwent five procedures before the Episealer® surgery and none of them worked.

"Immediately after the operation with Episealer® I was pain-free – it felt great! The following day I was already walking on crutches and a few weeks later I was able to walk normally without pain or swelling. Today I live a completely normal life. I can walk, go shopping all day or go for a long ride on my bicycle without exhaustion or swelling."

Post-operation:

- » Able to start working again
- » After 6 months, no pain at all and full function
- » After 12 months, no pain at all and full function

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 pilot 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 to Episurf Medical's team 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 µiFidelity®. 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 are the 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 and Episealer® Trochlea Solo and Episealer® Femoral received CE mark approval in 2013, 2014 and 2015, respectively. These are the world's first customised implants for treatment of cartilage damage in the knee joint. This is just the beginning of what Episurf Medical can do with its technology.

Business idea, goals and strategy

Episurf Medical was founded in 2009 and has developed and begun commercialising patient-specific orthopaedic implants for the treatment of painful knee joint injuries that address a large and fast-growing global market.

Before the end of 2016, the company plans to expand its current damage-marking process to offer an advanced 3D diagnostic report visualising cartilage, ligaments and underlying bone defects, otherwise invisible during arthroscopy. This comprehensive report, based on the MR images of the patient's knee joint, delivers an accurate pre-surgical picture of the knee, thereby creating the best conditions to plan for successful knee surgery including resurfacing of focal lesions. The same 3D model is used to design the customised Episealer® and Epiguide®.

We believe this enhanced clinical decision-making tool will deliver successful pre-surgical planning, improved patient outcomes and a compelling health economic value proposition.

Additionally, Episurf will define its US market entry strategy in 2016 while continuing to drive European commercialisation plans across the key markets of Germany, UK, Benelux and the Nordic region.

Strategic priorities in 2016

- » Consistent commercial execution.
- » Continued product and service innovation via our proprietary technology platform.
- » Producing scientifically robust clinical evidence.
- » Pursue the relevant regulatory and reimbursement pathways to support geographical expansion including an entry strategy into the US.

Business idea

Episurf Medical's business idea is to redefine the orthopaedic industry by offering an interactive web-based IT-platform that provides orthopaedic surgeons with a complete orthopaedic tech platform containing patient-specific 3D diagnostic tools, a pre-operative surgical report for patient-specific surgical pre-planning and patient-specific treatment solutions through implants and surgical tools.

The goal is to improve surgical precision and standardise the surgical procedure to deliver reliable, repeatable surgical outcomes for orthopaedic surgeons and excellent clinical outcomes for patients.

Vision

Episurf Medical's vision is to pioneer and mainstream innovative, clinically effective, cost-efficient patient-specific implants and surgical software tools as an early treatment option for patients with painful knee joints across a global market.

Goals and objectives

- » Episurf Medical's goals and objectives are to mainstream patient-specific treatment options as a new standard within the orthopaedic industry.
- » The goal is for surgeons to have seamless interaction with Episurf Medical's proprietary developed µiFidelity® system to facilitate clinical decision-making with advanced 3D damage-marking reports, surgical pre-planning and design of patient-specific treatment options. The ambition is to become the preferred choice for clinics and surgeons who wants to offer patient specific-solutions for early knee joint injuries.

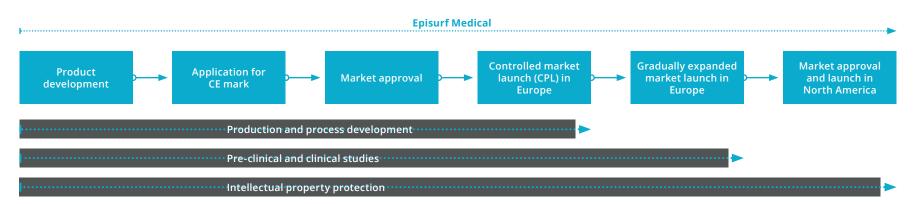
The company's patented implant technology and broad knowledge within knee joint injuries means Episurf Medical can offer patient-specific documentation for diagnostic assessment, a pre-surgical planning tool, design of implants as well as delivery of a "just in time" complete surgical tool-kit to surgeons for a simple and surgically precise procedure.

Strategy

Our strategic objective is for patient-specific implants to become the standard of care for focal cartilage defects, whereby Episurf implants deliver superior performance that offer improved clinical and health economic benefits for clinicians, patients and payers compared to off-the-shelf implants.

Historically, the industry has provided orthopaedic implants and surgical tools through a standardised assortment, i.e. "one size fits all-design". Episurf Medical is based on the simple idea that each implant and surgical instrument should fit and be designed for the patient rather than fitting the patient to the implant. Hence, the company's strategy is to develop and commercialise bespoke solutions for the treatment of early joint injuries and by doing so, giving individuals with painful joints a healthier and more active life. This strategy rests on six cornerstones.

Episurf Medical's development



[11]

1 μiFidelity® – patient-specific modelling and design on demand

Episurf Medical's proprietary web-based IT-system, µiFidelity®, delivers a visualisation support tool for patient-specific diagnostics of cartilage damage in knee joints and enables precision engineered production of patient-specific implants and surgical tools. Surgeons transfer unique patient MRI data to Episurf Medical's cloud-based platform for immediate and cost-efficient design and manufacture of patient-specific implants in a box that is shipped directly to the operating surgeon for surgery. The company's business model is based on on-demand manufacturing and just-intime delivery. This makes it possible to avoid inventory in all parts of the process.

Before the end of 2016, the company plans to develop an enhanced 3D damage-marking process for visualising chondral and osteochondral lesions in the femoral part of the knee, underlying bone defects, otherwise invisible during arthroscopy, and structural deviations on the tibia, patella, meniscus and ACL. The same 3D model is used to design the customised Episealer® and Epiguide®. In the event that Episurf Medical's implant solutions are considered an appropriate treatment option, a visualisation of the implant/guide will be added to the 3D image of the knee.

This comprehensive report, based on the MR images of the patient's knee, offers a surgeon a complete picture of the condition of the knee, thereby creating the best conditions to plan for successful knee cartilage repair surgery.

Through the surgeons' web-interface µiClinic, Episurf Medical currently offers the following services to surgeons:

- » Transfer of patient MRI scans,
- » 3D modelling and visualisation of each individual patient's anatomy and lesion (size, depth and location) including subchondral bone.
- » Assistance with pre-surgery planning via the design proposal for treatment and surgical methods, enabling a safe and simple surgical intervention, and
- » Order placement and follow-up.

2 The unique treatment method

By combining implant development expertise with patented patient-specific design and production technology, Episurf Medical offers implants and surgical tools customised for each individual patient's unique anatomy and cartilage lesion. The treatment method is primarily intended for patients suffering from attritional wear in knee joints and delivers pain-free mobility and improved quality of life whilst maximising bone preservation in the event of later treatments.

The method was developed in order to optimise the treatment outcome for the patient while at the same time simplifying the clinical process for the surgeon. By using the patient's MRI data as supporting documentation for correct placement of the implant, the surgeon can better localise and treat the areas giving rise to the pain.

Market feedback from our growing user base and clinical data indicates that we have solved the technical shortcomings of early resurfacing technologies. Episurf Medical's proprietary features, including the pre-surgical assessment of subchondral bone quality and opposing tibial cartilage, ensure that the Episealer® is used for the correct clinical indication. The patient-specific design delivers a custom fit that in turn ensures correct implant positioning. The one-piece implant design and proprietary HA and titanium coating ensure bone fixation.

3 Prioritised applications

The patient group suffering from initial cartilage damages up to early arthritis in the knee joint is large and fast-growing, and was considered an appropriate initial submarket entry point during Episurf Medical's start-up phase.

Over the past year, Episurf Medical has had early acceptance from surgeons of the Episealer® concept, surgical technique and products as a second line procedure for previously failed cartilage repair interventions. In 2016 Episurf Medical plans to mainstream the Episealer® procedure as a first line treatment for patients between 35 – 65 years of age with a diagnosis of early cartilage damage to initial arthritis.

4 Commercialisation strategy

We will further refine the Episurf Medical value proposition for key stakeholders: surgeons, patients and public and private payers. We believe our patient-specific knee implant product portfolio offers important clinical and economic benefits to patients, surgeons, hospitals and payers, which will in turn drive surgical adoption.

Potential benefits include

- » short procedure time,
- » reduced length of stay,
- » shorter rehab period,
- » improved patient outcomes, and
- » low complication rate.
- » Hospital systems can also benefit from our "implant in a box" offering and "deliver in time". which negate the need for sterilisation and stocking inventory.

We will expand our sales efforts through strengthening of our direct sales activity in the lead European markets – Germany and the UK. We have employed experienced orthopaedic sales professionals who have extensive knee surgeon networks. This approach will help decrease the time it takes for a new sales person to become productive.

We will continue performing systematic market analysis by building a quantified data base of key metrics across Europe and the USA, such as the number of knee specialists, centres of excellence, disease incidence and prevalence, procedure volumes, pricing, reimbursement and emerging and competitive technologies. We will grow our market presence by establishing relationships with high-volume knee specialist centres where surgeons are open to technology innovation. We will work with these surgeons to educate other surgeons. Our goal is to achieve low double digit market share penetration in the area of cartilage repair procedures over the coming years.

Our intent is to build a US market entry strategy following the mid-2016 conclusion of two key US regulatory and reimbursement planning projects.

We will work closely with our international Clinical Advisory Board to achieve four specific goals that will directly support our commercialisation activities:

- » To gain an expert understanding of the trends, drivers and priorities shaping clinical practice and the management of cartilage damage,
- » To continuously 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
- » To build robust and clinically evidenced patient outcome data.

5 Efficient protection of IPR

Episurf Medical is systematically building a strong patent portfolio to protect the company's technology and future products. The technology that creates patient-specific implants and instruments is supported by a strong patent portfolio with approximately seven patents and patent applications within the areas of image handling, patientspecific implant systems, patient-specific surgical techniques, patient-specific instrumentation and manufacturing for all of the body's joints. Episurf Medical is constantly working towards submitting new patent applications as the company grows and new products are created.

6 Profitable and scalable production

In order to reach the commercial goals, including longterm financial viability and geographical expansion, Episurf Medical's focus on customised treatment solutions must be combined with the ability to produce customised implants and tools in a more large-scale, cost-efficient manner. The current strategy is to manage all patient-specific design in-house and to use qualified external suppliers to manufacture the company's products. Since the start, the company has worked determinedly to develop and refine the processes for quality assurance in line with the Episurf Medical Quality Management System. All suppliers are connected to Episurf Medical's µiFidelity® system. To ensure sustainable, attractive gross margins as the business grows, we will evaluate:

- » How best to expand our digitally driven, just-in-time manufacturing process to enable large-scale, cost-efficient production of patient specific implants,
- » How to shorten product design and development timelines, and
- » How to continuously improve the products whilst reducing standard costs.



Episurf Medical's sales team, sales conference in Frankfurt in April 2016.

I want to create awareness of our technology among orthopaedic surgeons

Tell us about your background

I am a trained nurse and started my career in the operating room, scrubbing in during surgeries. My greatest interest was in orthopaedics, more specifically hip and knee replacements. Besides my caring nature as a nurse, I also liked the technical side of the job handling instruments and sophisticated equipment. Early on in my career, I developed a strong passion for scientific research and new techniques, which eventually led me to Episurf Medical.

Tell us about your work as a sales rep for Episurf Medical?

Most of my time, I am visiting orthopaedic surgeons to raise awareness about our Episealer® implants and how the technology can benefit their patients. In the beginning of customer relationships, I am also often present during surgeries in order to assist and answer questions. To be successful as a medical sales rep, I believe you need to know it all: anatomy, medical procedures, scientific work, competitive products. I have 22 years of experience from orthopaedics now, which is exactly half my life, and it is a great feeling when surgeons consider you an expert in the field. My basic ethics haven't change over the years; I am still a caring person who is now helping surgeons now to treat their patients, so indirectly helping the patients, with products I believe in.

Tell us about Episurf Medical's establishment in Benelux

At Episurf Medical, I cover Benelux. That means I am not only cover sales but also work with reimbursement. I started in September 2014 and commercial activities took off eight months later, after reimbursement was set up for our first

two implants. So far, we have done 22 procedures. Two of our Belgian centres set up a clinical study in which they are following the patients. So far, results are very positive.

I really want to take the opportunity to talk about our first patient in Belgium, operated three years ago. She was 36 years old at the time of surgery, had undergone five previous surgeries but was still in pain. She was told to be patient until she reached the appropriate age to receive a unicondylar knee implant. Naturally, she didn't want to wait that long as the pain and swelling kept her from doing her normal activities, both at work as well as at home. The pain also kept her awake at night. Remarkably, right after the surgery, she was pain-free. Her expectations were fulfilled, she simply wanted to get rid of the pain and the swelling so she could have a normal life again.

What kind of feedback do you get from surgeons in Belgium?

Surgeons very much appreciate the science behind our implants and our technology. From the start of Episurf Medical, the company has carried out extensive mechanical and animal studies in order to create a perfectly designed implant. However, not only is implant design important, it's also of the utmost importance to have it placed in the correct position and at the exact height. Our patient-specific instruments facilitate this and help surgeons to execute a perfect surgery.

What is different about Episealer® compared to alternative treatment methods you have worked with?

The Episealer implant is patient-specific, so there is only one implant per lesion. A surgeon doesn't have to choose



"So far, we have done 22 procedures in Belgium and the results are very positive."

Tania Bol Director of Sales Benelux

between implants during the surgery to see which would fit best. With standard implants, the surgeon always needs to make a compromise as no standard implant exactly matches the patient's anatomy.

We also perform thorough pre-operative planning. The MRI scan from the patient is evaluated by our engineers and a dedicated radiologist. They prepare a multi-page report of the cartilage and bone appearance in the knee which then goes back to the surgeon. With this report, the surgeon is able to pre-plan the treatment options and exclude any unwanted surprises during the surgery.

What do surgeons appreciate most about Episurf's offering?

Only few instruments are needed; this makes it an easy and straightforward procedure. All instruments are single-use, so there is no risk for blunt drills and no risk for cross infections.

Looking ahead - what's your focus going forward?

It's all about continuing to create awareness about Episurf Medical and the technology among surgeons. The clinical outcomes and the benefits for the surgeon are so convincing that I am very confident that Episurf Medical, as we broaden our surgery base, can help a significant number of patients suffering from severe knee pain to return to a normal life. And that's really important to me.

[13]

Our Clinical Advisory Board

During the year, Episurf Medical appointed a formal 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.



From left: Seppo Koskinen, Johannes Holz, Tim Spalding, Rosemary Cunningham Thomas, Mats Brittberg, Leif Ryd and Karl Eriksson.

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.

The Clinical Advisory Board consists of the following key opinion leaders in the fields of cartilage

[15]

Associate Professor Tim Spalding

United Kingdom

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

Associate Professor Karl Eriksson

Sweden

Department of Orthopaedics, "Sofiahemmet" Södersjukhuset, Stockholm.

Dr. Johannes Holz

Germany

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

Professor Seppo Koskinen

technology."

Finland/Sweden

Professor in Medical Radiology at the Department of Clinical Science, Intervention and Technology, Karolinska Institute, Senior Consultant, Karolinska University Hospital, Huddinge. Professor Mats Brittberg

Sweden

"The creation of a formal Clinical Advisory Board is a key milestone in the company's continuous efforts to implement our patient specific technology platform as an industry standard in Europe and globally. I'm delighted to welcome six industry 'superstars' to work with us in bringing people novel viable treatments based on cutting edge

> Professor, Cartilage Research Unit, Gothenburg University, Orthopaedic surgeon, Department of Orthopaedics, Kungsbacka Hospital, Kungsbacka.

Rosemary Cunningham Thomas,

CEO of Episurf Medical.

Associate Professor Leif Ryd

Orthopaedic surgeon with a long career in clinical research on osteoarthritis. Former professor at Karolinska Institutet.

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.

[16]

Osteoarthritis 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 in 2016 are primarily intended for patients in the age range of 35–65 years who need to guickly return to an active life, and for patients regardless of age who also suffer from underlying bone damage (osteochondral defects). There is a significant patient group with focal cartilage lesions of traumatic or degenerative origin (pre-arthritic) that today lacks adequate treatment alternatives and is in urgent need of effective new treatment methods.

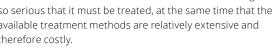
An estimated 3.6million patients worldwide have symptomatic knee osteoarthritis and are found in the large socalled "treatment gap". These are patients at an active age with early-stage unilateral osteoarthritis. They are too young and active for knee replacement surgery, but are too old and have too extensive damage for treatment with traditional

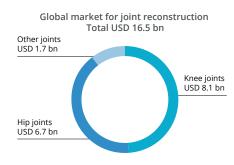
methods for cartilage defects. Studies in the USA show that the average age of those suffering from osteoarthritis fell from 72 to 56 years between 1990 and 2010, a full 16 years over the course of two decades.

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 16.5 billion in 2015. As a segment of this wider market, the market for knee products is the single largest and is worth approximately USD 8.1 million. Within this market, knee implants are the largest product in absolute terms. Episurf Medical has established itself is this market with a primary focus on treatment of cartilage and joint damage of traumatic or degenerative origin from early cartilage lesions to initial osteoarthritis, which in untreated condition leads to full-scale osteoarthritis. At present, the largest market for treatment of joint problems is that for late-stage

osteoarthritis. This is because the condition at that stage is so serious that it must be treated, at the same time that the available treatment methods are relatively extensive and therefore costly.





Source: The orthopaedic industry annual report 2015

Ten per cent of the US population over the age of 25 has signs of osteoarthritis in their joints, of which it is estimated that half are located in the knee. According to studies, 5 per cent of the US population over the age of 50 is living with a prosthetic knee joint.

Over the past decade, the number of knee replacement procedures on patients under the age of 65 years has increased dramatically. The ten largest markets for knee replacement surgery are the USA, France, Germany, Italy, Spain, the UK, Japan, Brazil, China and India. Some 1.5 million surgeries are performed every year in these markets. In 2013 some 800,000 knee replacement surgeries were carried out in the USA alone, which is more than a doubling in only 10 years.

The implants used in knee replacement surgery have an expected longevity of 15–20 years and in light of this, most orthopaedic surgeons today recommend that patients wait until they have reached the age of 65 before undergoing this surgery. Furthermore, at present a very 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 USA is around 60,000, less than 10 per cent of all knee replacements, and the number in Europe is around 50,000 per year. Here there is an enormous unrecorded number of patients in need of help. There is an increasing trend of knee replacements on a global basis, with 2.6 million knee replacements performed in 2015, compared to 1.9 million in 2010.

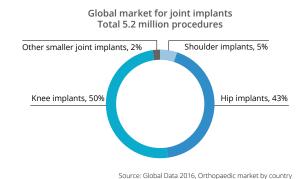
Episurf Medical's primary market potential – cartilage damage in the knee joint

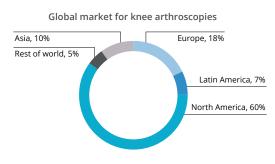
Every year, around 6.5 million knee arthroscopies are performed worldwide and this number is expected to grow by an average of 7 per cent annually over the next five years. In the USA alone, some 3.7 million knee arthroscopies are performed every year. The corresponding figure for Europe is 1.1 million per year. Research shows that of these, between 7–13 per cent are found to have traumatic or degenerative cartilage defects of grade III and IV. Today it is assessed that around two-thirds of these are treatable with Episurf Medical's CE-labeled products Episealer® Condyle Solo and Episealer® Trochlea Solo, Episealer® Femoral Twin and

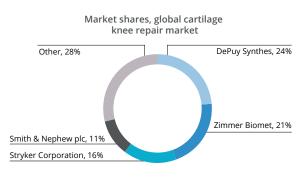
Epiguide® MOS, depending on the location of the injury in the knee joint, the patient's age and the extent of the injury. Hence, the estimated market potential amounts to approximately USD 3.5 bn over the coming years.

The cases where Episurf Medical's products are used for treatment of patients in which arthroscopic treatment such as microfracture or debridement has failed, this represents a potential market of around 400,000 cases per year given that around 30 per cent of all procedures fail within two years after completion of treatment. The incidence is around 330,000 cases per year in the USA and 110,000 in Europe. Hence, the estimated market potential amounts to approximately USD 0.9 bn over the coming years.

Episurf Medical's implants are designed to treat the patient's entire injury, both the cartilage and the 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 biological methods. This indicates a high probability that the company's implants will be increasingly accepted as the first line method for treatment of cartilage defects of grade III–IV, which means that the market potential for Episurf's products is growing.







Source: Transparency market research 2016

Source: Transparency market research 2016

Existing treatment gap

Since the existing treatments to repair cartilage damage are given primarily to younger patients (under 35 years), the only options for patients over the age of 35 are non-surgical treatment methods or, in later stages of the disease, replacement of the joint through surgery. A 35-year-old patient with severe pain and stiff joints resulting from cartilage damage may be forced to live with chronic joint pain and limited mobility for several decades before qualifying for knee replacement surgery. For this patient group, the existing treatment methods are inadequate and there is an urgent need for ways to treat this damage effectively when it arises. Furthermore, there are no reliable treatment methods for younger patients who value short and rapid rehabilitation so that they can return to an active life.

Market drivers

The market for treatment of cartilage and bone tissue damage is driven primarily by an aging population, a rising average body weight and technological advances in the design and manufacture of implant components that offer wider treatment options. 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. 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. The corresponding figure for 2015 is estimated at 2.3 billion overweight and more than 700 million obese.

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.

Treatment alternatives for joint damage and osteoarthritis

Today there are both non-surgical and surgical treatment methods for osteoarthritis and joint damage that precedes osteoarthritis. Although there is no universally effective method that can cure or stop osteoarthritis, the symptoms can be alleviated. All of the current treatment methods have one or more significant drawbacks in terms of both the treatment itself as well as quality of life, safety and longevity after treatment.

The surgical treatment methods include joint replacement surgery (knee implants) and biological solutions, so-called regenerative surgery aimed at stimulating cartilage healing, such as microfracture (performed during arthroscopy), mosaicplasty and autologous chondrocyte implantation (ACI). One thing the biological treatment methods have in common is that the outcome is uncertain, the rehabilitation is long and they become less effective as the patient grow older, i.e. when the patient has passed the age of 35–40.

The most common surgical treatment for middle-aged and older patients is knee replacement surgery. The outcomes for most patients are satisfactory in terms of alleviating pain and mobility is increased in many cases, although still limited compared to a person with a healthy joint. As a rule, the surgery requires 6-12 months of rehabilitation and the implant has a limited longevity of 15–20 years. In view of this, knee replacement surgery is normally not offered to patients below the age of 65.

Debridement/microfracture

In 2009 some 170,000 knee cartilage restoration procedures were performed in Germany, England, Spain, Austria, Italy and France, of which the majority consisted of debridement/ microfracture since these are relatively simple and inexpensive to perform. Cartilage restoration is often used as a first line of treatment for early-stage cartilage damage.

The long-term effects of debridement and mircrofracture procedures have been called into question, since many consider them to be renovation rather than restoration. Because the underlying condition is not treated, the symptoms can return. In most cases, a microfracture procedure is not successful in recreating hyaline cartilage (natural cartilage). Instead, the body forms fibrocartilage (scar tissue) that has lower durability than hyaline cartilage. These treatments also require long rehabilitation during which the cells can grow to fill the defect and mature. The full effects cannot be expected until after two years.

Autologous chondrocyte implantation (ACI)

Around 4,000–5,000 ACI procedures are performed in Europe every year, with annual growth of around 5 per cent. Given an average sales price of around EUR 20,000, this represents an estimated market value of approximately EUR 80 million annually. ACI is a two-step method that is suitable for younger patients (under 35 years) and for patients who have no problems with underlying bone damage. This treatment also requires long rehabilitation during which the cells grow to fill the defect and mature. The full effects cannot be expected until after two years.

According to new regulations that were introduced in Europe in 2008, these products are now classified as pharmaceuticals and not medical devices. The industry was given four years to meet the requirements in the new regulations. This costly process has caused many players to disappear from the market and led to dramatically higher prices, which have in turn made it more difficult to receive reimbursement for the products and increased the demands on clinical

A cartilage tissue transplant is carried out in two steps. In step 1, a procedure is performed in the patient's knee to harvest healthy cartilage cells which are then cultivated in a laboratory. Step 2 takes place a few weeks later when new cartilage cells are implanted into the patient's defect. Cartilage tissue transplants are regarded as a premium product

due to their complexity and high price, which means that many healthcare systems lack sufficient resources to cover procedures of this type.

Cell-free treatment methods

Cell-free treatment methods, also known as one-step methods, are relatively new treatments for cartilage defects that are gaining rapid popularity in Europe due to their advantages over two-step methods. As the name indicates (one-step), in this method the cartilage that is taken from the patient during the surgery is immediately implanted into the patient. Cell-free one-step procedures are suitable for younger patients (under 35 years) and for patients who have no problems with underlying bone damage, so-called osteochondral damage. The procedure costs for these products are significantly lower than for two-step methods, since they require only one surgery and no cultivation of cells in a laboratory. A lack of clinical data and long-term data on how the quality of the newly formed cartilage changes over time is limiting the rate of adoption of these methods.

Osteochondral autograft transfer (mosaicplasty)

Osteochondral autograft transfer procedures are also known as mosaicplasty. During these procedures, healthy cartilage and bone is removed from a less weight-bearing area of the knee joint and then implanted into the site of the defect. The procedure is relatively affordable and is growing in popularity, although it is considered technically challenging to perform. It is difficult to find healthy cartilage that is suitable for the damage area, and the site from which the transplant is harvested can create new problems for the patient. Osteochondral autograft procedures are indicated for younger patients (under 35 years) and for patients who also have problems with underlying bone defects (osteochondral damage). The number of osteochondral autograft procedures in the five largest European markets is estimated at around 6,500 per year.

Competing joint replacement implants

Episurf Medical's patient-specific Episealer® implant belongs to an implant category known as "Resurfacing implants". These implants are aimed at treating cartilage and osteochondral damage in a patient's joints so that the defect is repaired with an implant to directly recreate the original weight-bearing joint surface for pain relief, maximum mobility and minimum rehabilitation.

Other resurfacing implants on the market include Arthrosurface's Hemicap implant. Arthrosurface is a US-based company that develops and manufactures off-the-shelf implants for cartilage defects and damage in major joints. The company develops products for the knee, hip, ankle, toes and shoulder, and, like Episurf, focuses on minimally invasive surgery. By 2015 approximately 12,000 patients had already received the company's knee implants. Schwarz Biomedical also has a resurfacing implant that is part of a product family known as Biopoly, which, like Arthrosurface's products, consists of kits of standard sizes. Biopoly was introduced relatively recently in the European market.



Our knee portfolio

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

[20]



Episurf Medical's product portfolio for knees includes products that can be used to treat patients in the age group 20–65 years with knee joint injuries of most types and sizes, from initial cartilage damage to early arthritis.

By combining advanced 3D imaging technology with the latest manufacturing technology, we are able to adapt not only each implant the patient's unique injury and anatomy, but also the surgical instruments used. In this way, we can ensure that every 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.

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 in individualised treatment technology. The company's technology can be applied to joints other than the knees, such as the ankles, shoulders, toes and even hips, and can thus give rise to additional product portfolios for specific areas of use.

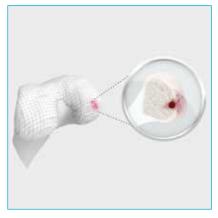
μiFidelity®system

From MRI to customised implant and surgical tools.

Episurf Medical's µiFidelity® is first in the world to deliver 3D visualisation support for patient-specific diagnostics of cartilage damage in knee joints and precision engineered production of patient-specific 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.
- The treating physician decides on the best treatment method.



- 6 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.



- 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.



Ouring 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.

Episealer® customised 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. They can be easily inserted, cause minimal trauma to the surrounding issue and require less complicated rehabilitation than the other treatment alternatives. Furthermore, since healthy cartilage and bone are preserved, the patient's options for future interventions such as knee replacement surgery are not limited. The Episealer® implants primarily target patients in the age group 35-65 years.

Episurf Medical's method tailors the implant to each individual patient instead forcing the patient to fit the implant, as is traditionally done in joint replacement 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 longterm outcomes of a procedure.

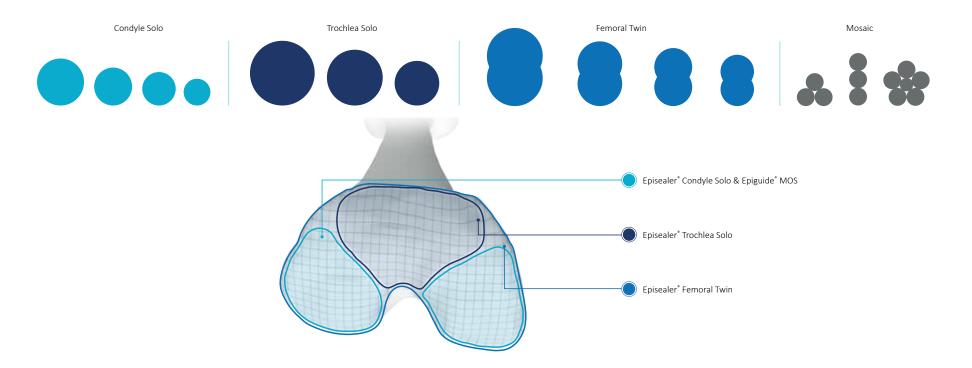
Episealer® implants are small, thin and adapted to each individual's unique anatomy and injury. They are made of a cobalt-chrome alloy with a central peg for initial fixation. Cobalt-chrome is a material that has been used in knee prostheses for more than two decades and has been proven to provide a safe, effective and weight-bearing joint surface. The part that is anchored in the underlying bone has a undercoating of titanium and a bioactive outer coating of hydroxyapatite that results in stable and long-term fixation in the bone.

Episealer® Condyle Solo

Resurfacing implant for treatment of localised cartilage and bone defects in the knee joint. The implant is the company's first commercial product and market approval was obtained in 2013 in the form of CE marking. Market introduction is taking place through a controlled product launch (CPL) in selected orthopaedic clinics in Northern and Central Europe.

Episealer® Trochlea Solo

Resurfacing implant for treatment of localised cartilage and bone defects in the in the area behind the patella (kneecap). The implant is the company's second commercial product and market approval was obtained in 2014 in the form of CE



marking. Market introduction is taking place through a controlled product launch (CPL) in selected orthopaedic clinics in Northern and Central Europe.

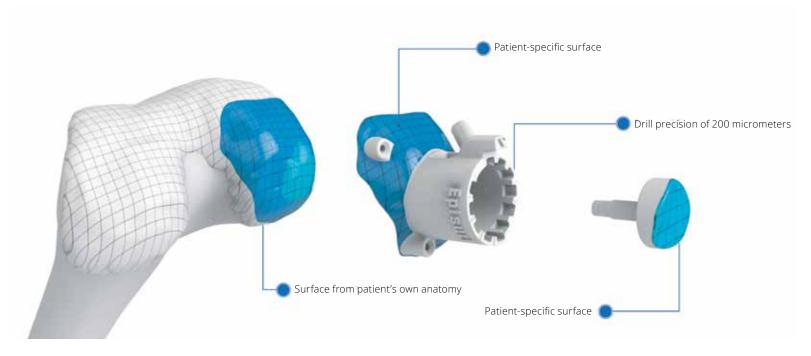
Episealer® Femoral Twin

Resurfacing implant developed to fit more patients with different types of cartilage damage, primarily larger and more elongated defects and damages in more complex areas of the knee joint where circular implants are not suitable. The product is was approved for CE marking and was launched on the European market in 2015.

Market launch	Product line	Age range		Indications
		20-40	35-65	
CE mark approval	Episealer® Condyle Solo		•	Osteochondral defects of grade III–IV
CE mark approval	Episealer® Trochlea Solo		•	Osteochondral defects of grade III–IV
CE mark approval	Episealer® Femoral Twin		•	Osteochondral defects of grade III–IV
CE mark approval	Epiguide® MOS	•	•	Osteochondral defects of grade III–IV

Epiguide® surgical drill guides

Customised surgical tools for high precision



To ensure simple and fast surgery and optimal positioning of the implant, Episurf Medical designs surgical tools in the form of customised drill guides, Epiguide®. They are designed according to patient-specific data in the same way as the Episealer® and are 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, so that these are not a matter of judgement for the surgeon. Epiguide® guides the surgeon through the entire procedure, simplifies execution and increases precision. Epiguide® is designed and used together with all of the company's implant products.

Epiguide® MOS

Patient-specific drill guide for mosaicplasty

Epiguide® MOS is a patient-specific drill guide that is being developed for younger active patients in the age group 20–40 years with painful cartilage defects in the knee joint. Traditional mosaicplasty is done by free hand technique. Mosaicplasty is generally considered to be a technically challenging procedure.

The Epiguide® MOS drill guide is a product that is intended to guide the surgeon and to facilitate, streamline and standardise the surgical procedure. In mosaicplasty, cartilage or bone grafts are removed from a less load-bearing region of the knee joint in order to fill the cartilage defect. Because the guides are customised and based on MRI data from the patient's injury, it is possible to achieve more precise placement and filling of the defect than in traditional mosaicplasty. The procedure is also simpler and faster for the surgeon to perform.

Epiguide® MOS has been approved for CE marking and was launched in selected orthopaedic clinics in Northern and Central Europe during 2015.



How we design patient-specific implants







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What areas of expertise are found in Episurf Medical's design team?

We are all engineers with backgrounds in design, product development, software development, image analysis and medical technology. We have different backgrounds and specialities, and complement each another in the various parts of the design process.

How do you collaborate with surgeons?

Through the µiFidelity® platform we have direct contact with the surgeons. All of the surgeons we work with are connected to an account in µiFidelity®, and this is where all communication takes place.

We see immediately when they place an order and can then start processing the MR images. When we have created a design proposal for a product, we upload it to the surgeons for approval in µiFidelity®.

What happens when a surgeon places an order?'

The surgeon creates a new order in µiFidelity® for each patient and uploads the patient's MRI scans. If we feel that the injury is suitable for an Episealer®, we send back a proposed implant placement, shape and size in the form of a damage assessment report. The surgeon can then analyse the proposal in detail and discuss it with the patient.

Our report shows the implant both as a 3D visualisation of the knee joint and as the contours of the implant projected onto the patient's own MR images. This makes it easy for the surgeon to see how the implant will be placed and how much of the defect will be covered. It is always the surgeon that makes the final decision. And if the surgeon wants to make any changes in the placement, shape or size, we put together a new proposal that meets the surgeon's specifications.

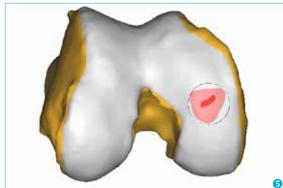
How does the company determine whether a patient is suitable for an Episealer®?

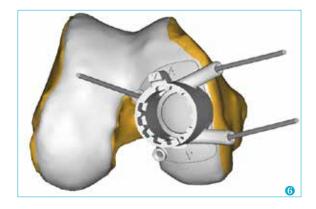
We analyse the patient's MRI data together with a radiologist. In the images, we mark damage on the femur's cartilage and bone surfaces. We also assess other defects in the knee, such as meniscus and tibia damage. If the patient has a focal cartilage defect that can be covered with an Episealer® and there are no contraindications, we make a proposal for an Episealer® design.

How do you analyse the MRI scans?

From each patient we receive six different series of MR images. They are taken in different slices and with different contrasts that highlight different types of defects. Together with a radiologist, the site of the defect is drawn directly into the MR images and combined so that information from all image series contributes to the final assessment. In the images it is also possible







to see damage in the surrounding tissue, and this allows us to make an overall evaluation of the knee's condition.

Tell us about Epioscopy's™ role in the design process

We analyse both cartilage and bone damage. Unlike an arthroscopy, where a small camera is used to look inside the knee, the MRI scans enable us to see damage located inside the bone. Cartilage has no nerve cells, so the source of the pain is often the bone. By looking at all levels, we can get a more complete picture of the defect and treat the underlying damages more effectively.

How is the choice of Episealer® determined?

We analyse the shape and size of the defect and make a proposal for a suitable Episealer®, taking both cartilage and underlying bone defects into consideration.

How are the manufacturing specifications prepared, i.e. the specifications for production?

Based on the MRI data, we create a 3D model of the patient's knee in which cartilage and bone are visualised. Based on the patient's healthy joint surface, a new damage-free surface is recreated, after which the patient-specific implant (Episealer®) and the surgical kit (Epiguide® and Epidummy) are designed.

The 3D files are then sent to the ISO13485-certified manufacturers, where the guides are 3D-printed and the implant is produced through turning and milling. After sterilisation, the patient-specific Epikit is sent to the responsible surgeon ahead of the procedure.

- Ingrid Bratt and Jonas Jägerback,
 Episurf Medical's production team.
- Through the µiFidelity® platform we have direct contact with the surgeons.
- Our report shows the implant both as a 3D visualisation of the knee joint and as the contours of the implant projected onto the patient's own MRI scans.
- 4 MR image with segmentation contour.
- 3D model of a knee together with the contour of an Episealer®.
- 3D model of a knee with Epiguide®, Episealer® and surgical pins.

The Episurf Medical Group consists of Episurf Medical AB (publ) and the wholly owned subsidiaries Episurf IP-management AB, Episurf Operations AB, Episurf Europe AB, Episurf DE GmbH and Episurf UK Ltd.

The average number of employees in the Group during the year was 17, of whom seven women and ten men. The number of employees in the Group at the end of 2015 was 19, which is an increase of five employees compared to year-end 2014

Despite it 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

Organisation **Board of Directors Executive** CEO Management **Accounting & Finance** Research & Image analysis & **Production &** Sales & **Clinical studies** QA/RA¹ **Development** 3D modification Logistics Marketing

1) Quality Assurance/Regulatory Affairs

additional expert knowhow 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 is adding more functions to the in-house organisation.

In pace with Episurf Medical's development in a commercial direction, the organisation is being adapted and in 2015 several new employees were recruited, primarily in marketing and sales. The international sales organisation has been increased by four sales professionals, two in Germany and two in the UK, which together with Benelux will make up Episurf Medical's main markets in 2016. At the beginning of 2016 an additional six people were employed in the sales organisation.

In order to strengthen the company's focus on commercial expansion, changes have also been made in the company's management team. In June 2015 Rosemary Cunningham Thomas replaced Nina Bake as CEO and in December 2015 Pål Ryfors was appointed as CFO, after which both are members of the company's management team. The company's management team now consists of three people, CEO Rosemary Cunningham Thomas, CFO Pål Ryfors and COO Jeanette Spångberg.

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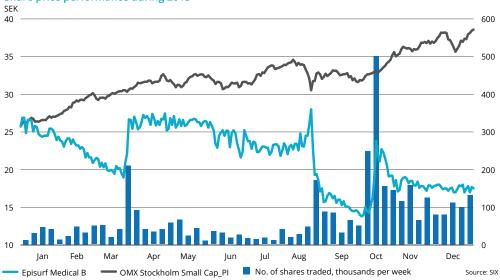
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Share and ownership structure

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



Share price performance during 2015



Share and share capital

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 7,956,579, of which 1,761,333 were class A and 6,195,246 were class B shares. The total number of shares at year-end 2015 was 15,963,305, of which 3,470,769 were class A shares and 12,492,536 were class B shares. The total number of votes was 22,911,824.

When Michael McEwan left his position as CCO of Episurf Medical in August 2015, he surrendered, without compensation, 13,501 of the 16,877 class B shares that were issued to him by the decision of the 2015 Annual General Meeting (AGM). (The company intends to propose that the 2016 AGM resolve to cancel these 13,501 shares through reduction of the share capital). The number of shares outstanding at 31 December 2015

The ten largest shareholders in Episurf Medical AB at 31 December 2015

Name	Class A shares	Class B shares	% of capital	% of votes
Serendipity Ixora AB	2,822,563	0	17.7	37.0
Nordea Investment Funds	56,033	1,191,097	7.8	5.9
Gile Medicinkonsult AB	254,945	128,454	2.4	3.9
Försäkringsaktiebolaget, Avanza Pension	0	834,380	5.2	3.6
Rhenman Healthcare L/S Fund	0	688,178	4.3	3.0
AMF – Försäkring och Fonder	0	620,224	3.9	2.7
LMK Forward AB	0	600,000	3.8	2.6
Lönn, Mikael	106,179	280,000	2.4	2.6
Kaupthing HF.	0	501,334	3.1	2.2
Robur Försäkring	0	422,962	2.7	1.9
Total, 10 largest shareholders	3,239,720	5,266,629	53.3	65.4
Total, others	231,049	7,225,907	46.7	34.6
Total number of shares	3,470,769	12,492,536	100.0	100.0
Of which, held in treasury		13,501		

Ticker symbol	EPIS B
ISIN code AK A:	SE0003523869
ISIN code AK B:	SE0003491562
Order book ID:	78419
No. of shares outstanding:	15,963,305
Quota value:	SEK 0.30
Round lot:	1 share
Share capital:	4,788,991.50

was thus 15,949,804 and the number of class B shares was 12.479.035.

The share capital at 31 December 2015 amounted to SEK 4,788,991,50, with a quota value of SEK 0.30 per share. According to the Articles of Association, the share capital shall amount to no less than SEK 1,920,000 and no more than SEK 7,680,000, divided between no fewer than 6,400,000 shares and no more than 25,600,000 shares.

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.

Two private placements were carried out during the year, one at the beginning of June to CCO Michael McEwan that consisted of 16,877 class B shares with a subscription price of SEK 35.55 each. The private placement increased the share capital by SEK 5,063.10 and had a dilutive effect

of around 0.21 per cent of the total number of shares in the company. The second private placement was carried out at the beginning of September to CFO Pål Ryfors and consisted of 16,393 class B shares with a subscription price of SEK 34.84 each. This private placement increased the share capital by SEK 4,917.90 and had a dilutive effect of around 0.20 per cent of the total number of shares in the Company.

During the financial year Episurf Medical also carried out a rights issue with pre-emptive rights for the company's shareholders. The new class A and class B shares were issued with a subscription price of SEK 15 each. The subscription period ran from 26 August 2015 to 10 September 2015.

The final outcome shows that 97.8 per cent of the new shares were subscribed by shareholders through primary and subsidiary pre-emptive rights. The total count shows that 6,917,407 shares (of which 1,550,892 were class A and 5,366,515 were class B shares), equal to 86.8 per cent of the offered shares, were subscribed through the exercise of subscription rights, while 881,226 shares, equal to 11.05

per cent of the offered shares, were subscribed without the support of subscription rights. The remaining 174,823 shares, equal to 2.2 per cent of the offered shares, were allocated to the individuals who had guaranteed the rights issue pursuant to agreements with the company. The rights issue was thus fully subscribed and the company raised approximately SEK 120 million before issue expenses. Through the new share issue, Episurf Medical's share capital increased by SEK 2,392,036.80. The number of class A shares increased by 1,741,228 and the number of class B shares increased by 6,232,228. The total number of shares thus increased by 7,973,456 and the total number of votes by 11,455,912.

Share price performance and trading

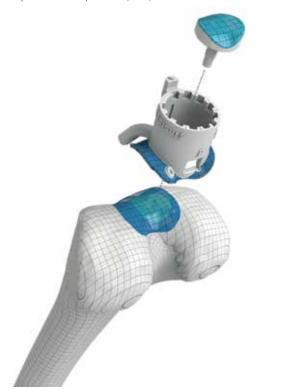
Episurf Medical's share price at year-end 2015 was SEK 17.5 (35.7), which is equal to a market capitalisation, calculated on the total number of class A and B shares, of SEK 279.4 million (284.0). During the financial year, the share price changed by –27.0 per cent (–46.7). The highest price paid

during the year was SEK 31.4 (84.5) and the lowest was SEK 12.6 (25.4). In 2015, 3,788,822 class B shares were traded on Nasdaq Stockholm (2,665,108 including Nasdaq Stockholm First North) for a total value of SEK 77.3 million (150.9).

Ownership structure

The number of shareholders at year-end was 1,940 (1,444). The ten largest shareholders in Episurf Medical in terms of voting power held shares corresponding to 53.3 per cent (48.9) of the share capital and 65.4 per cent (61.6) of the

The largest shareholder, Serendipity Ixora Fund AB, held shares corresponding to 17.7 per cent (17.2) of the share capital and 37.0 per cent (35.8) of the votes.



Ownership structure by size of holding at 30 December 2015

Holding	No. of share- holders	Class A shares	Class B shares	% of capital	% of votes	Market value (SEK 000s)
Holding						
1-500	940	4,500	173,155	1.1	0.8	3,030
501-1,000	311	2,780	245,593	1.6	1.1	4,298
1,001-5,000	474	19,621	1,129,844	7.2	5.2	19,772
5 001-10,000	86	12,914	606,282	3.9	2.8	10,610
10,001-15,000	33	11,112	392,344	2.5	1.9	6,866
15,001-20,000	20	41,762	316,233	2.2	1.9	5,534
20,001-	76	3,378,080	9,629,085	81.5	86.3	168,509
Total	1,940	3,470,769	12,492,536	100.0	100.0	218,619

Development of the share

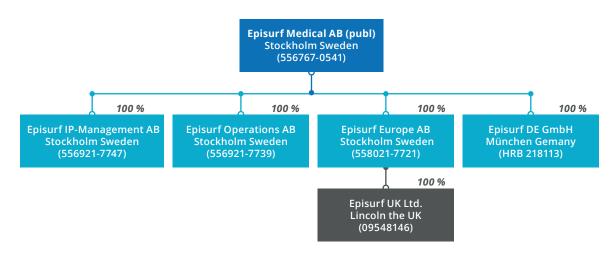
Year	Event	Quota value	Increase in the no. of shares	Increase in the share capital	Total no. of shares	Total share capital
	Formation of					
2008	company	0.01	10,000,000	100,000	10,000,000	100,000
2010	New share issue	0.01	800,000	8,000	10,800,000	108,000
2010	Bonus issue	0.05	-	432,000	10,800,000	540,000
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	Merger	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 issues	0.30	8,006,726	2,402,017	15,963,305	4,788,991

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 2015 to 31 December 2015.

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Group structure



Group structure

The Group consists of the Parent Company Episurf Medical AB (publ) and the four wholly owned subsidiaries Episurf IP-Management AB, Episurf Operations AB, Episurf Europe AB, Episurf DE GmbH and Episurf UK Ltd, a wholly owned subsidiary of Episurf Europe AB.

General information about operations

Episurf Medical, founded in 2009, 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. The share (EPIS B) is listed on Nasdaq Stockholm since 11 June 2014.

Product portfolio

Episurf Medical has developed a platform for the design and manufacture of patient-specific implants (Episealer®) and surgical drill guides (Epiguide®) for the treatment of painful joints. The Episealer® implant caters primarily to patients in the age category of 35–65 years with focal cartilage and bone tissue defects of traumatic of degenerative origin, and is aimed at bridging the gap between conservative treatment methods, early stage surgical procedures and knee replacement. The scalable µiFidelity® system is a proprietary web-based IT system that has been developed for diagnostics, surgical pre-planning and cost-effective patient customisation. The system is the first in the world to enable precision-engineered production of patient-specific implants and surgical tools.

At present Episurf Medical has four products approved on the European market, Episealer® Condyle Solo and Episealer® Trochlea Solo. Episealer® Femoral Twin and Epiguide® MOS, for the treatment of cartilage damage of different sizes in the knee joint and treatment of active patients at younger ages (20–40 years).



Research and development

Episurf Medical's product development is conducted according to a proven model that has been tested and proven through the company's first commercial products, the patient-specific implants Episealer® Condyle Solo and Episealer® Trochlea Solo. Leading orthopaedic surgeons and researchers are engaged at an early stage of development to identify clinical needs and patient benefits. Throughout the development process, the company maintains a close dialogue with the 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.

Since the autumn of 2012, Episurf Medical has been conducting a clinical trial with the aim of evaluating the personalised implant Episealer® Condyle Solo for the treatment of focal cartilage lesions in the knee joint. The study is being conducted in collaboration with four orthopaedic clinics in Sweden. The main study parameters are pain and function. At year-end 2015, a total of nine patients had been recruited and received implants in the study.

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 being introduced in a first step to selected leading clinics and surgeons primarily in Northern and Central Europe

through a controlled product launch (CPL), in which all operated 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 2016 will continue to be the UK and Germany. In addition, preparations are underway for the launch of a knee product portfolio in North American within one to two years. The launch in North America may be carried out together with a partner.

Significant events during the financial year

- » Changes were made in the organisation and management team in order to strengthen the company's focus on commercial expansion. Rosemary Cunningham Thomas took over as the new CEO.
- » The first surgeries with the Episealer® Condyle Solo implant in the UK were performed with successful results.
- » The beta version of the Lite Assessment service was launched at the same time that a new graphic identity and a new website were implemented.
- » A Belgian patient with a 10-year history of knee problems and a number of unsuccessful interventions was symptom-free after receiving an Episurf implant.
- » Episurf Medical's quality management system was certified according to ISO 13485:12 and Annex II.
- » The Episealer® Condyle Solo implant was included in the Belgian reimbursement system.
- » The first compilation of monitoring data from the company's ongoing controlled product launch showed improvements on all points according to the two measurement methods VAS and KOOS.
- » The AGM resolved to introduce a combined bonus and incentive program for all employees of the company.
- » The company started direct sales in Germany and the UK.

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- » Episurf Medical received another US patent relating to the company's surgical kit that consists of the patient-specific guide, Epiguide[®], and related surgical tools, Epikit.
- » An extraordinary general meeting on 21 August 2015 resolved on a new share issue of up to SEK 120 million with preferential rights for the company's shareholders and a private placement of class B shares to the company's new CFO.
- » Michael McEwan, Chief Commercial Officer (CCO) and member of the company's executive management, left his position with effect from 31 August 2015.
- » CE mark approval was received for the company's third implant, Episealer® Femoral Twin, which was the first "self-certified" CE mark for a product through the company's recently obtained ISO 13485:2012 and Annex II certification. Epiguide® - Enabling Correct Implant Placement.
- » The new share issue that was completed on 10 September 2015 was subscribed by 97.8 per cent of the shareholders and the company raised SEK 120 million before issue expenses.
- » The company's sales and marketing activities were intensified through increased participation in European orthopaedic conferences.
- » Episurf Medical received CE mark approval for its fourth product, Epiguide® MOS.
- » Episurf Medical appointed a Clinical Advisory Board consisting of European Key Opinion Leaders.
- » Episurf Medical's first surgery in Switzerland was successfully completed.
- » The first two surgeries with Episurf Medical's latest product, Episealer® Twin, were performed in Germany with satisfactory results.

Significant events after the end of the financial year

- » Episurf Medical received CE mark approval for its fifth product, Epioscopy™ Damage Assessment Tool.
- » Episurf Medical launched a German website and intensified its marketing activities in the region.
- » Episurf Medical announced that the company now has 100 users approved and connected to the µiFidelity® platform.

- » The scientific abstract "On the attachment of cartilage to HA: Signs of "chondrointegration" Studies on the Episealer® mini-prosthesis in the sheep knee" was granted a poster presentation at orthopaedic conference ESSKA.
- » A fourth sales representative was hired in Germany.
- » A second sales representative was hired for the Nordic
- » Episealer® was approved by Spire Hospital in the UK for private insurance patients.

Employees

At 31 December 2015 the Group had 19 employees (14), of whom employees in the Parent Company Episurf Medical AB amounted to 12 (9). Personnel costs amounted to SEK 26,834,214 (12,536,904) in the Group and SEK 14,968,281 (9,401,693) 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 focus continuously 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 manufactured, distributed and handled for use in the healthcare sector.

Episurf Medical's environmental policy is to include environmental consideration as an natural component of the company's operations. Episurf Medical has no in-house production, which means that its operations have a very limited impact on the environment and local community. With regard to production of Episurf Medical's products, the company will work with suppliers whose production facilities are certified and meet the company's ethical, environmental and occupational health and safety criteria. Being open and providing the shareholders and stakeholders with full transparency is a top priority for Episurf Medical. Accordingly, up-to-date and relevant information will always be available on the company's website under the tab IR. Here, stakeholders and shareholders can find clear, complete and reliable information the meets all of their needs, regardless of their level of expertise. Communication with the shareholders and stakeholders takes place via the website, newsletters and press releases.

Through structured board work, Episurf Medical ensures that corporate responsibility issues are addressed and included on the management's agenda.

Investments in the Group

The year's investments amounted to SEK 7,376,387 (2,869,537).

Investments in the Parent Company

The year's investments amounted to SEK 4,646,489 (499,976).

Consolidated income and expenses

Net sales

Consolidated net sales for the period from 1 January 2015 to 31 December 2015 amounted to SEK 1.016.462 (173.026).

Expenses

The Group's expenses for the period from 1 January 2015 to 31 December 2015 amounted to SEK 50.653.579 (35,600,753).

Profit

The consolidated operating loss for the period from 1 January 2015 to 31 December 2015 was SEK –44,008,519 (–33,261,259). The loss after financial items was SEK –43,974,662 (–32,914,421). The loss consists mainly of expenses for development, marketing and sales activities related to the company's controlled product launch. The company has been awarded a grant from Vinnova of SEK 4,200,000, of which SEK 949,104 (1,692,450) has been recognised in revenue, which corresponds to accrued expenses.

Financial position and liquidity

Consolidated cash and cash equivalents at year-end 2015 amounted to SEK 103,960,776 (34,489,799). Cash flow from operating activities before changes in working capital was SEK-41,739,636 (-31,153,378). Consolidated equity at year-end amounted to SEK 109,934,539 (38,849,577) and the equity ratio was 93.0 per cent (89.8).

Parent Company - Episurf Medical AB (publ)

Net sales in the Parent Company for the financial year from 1 January 2015 to 31 December 2015 reached SEK 754,609 (195,978). Operating expenses amounted to SEK 28,507,567 (26,066,269). The increase in expenses compared to the previous year is mainly due to a higher pace in development, clinical trials and marketing activities. The operating loss was SEK –22,125,310 (–23,703,823) and the loss after financial items was SEK –21,709,809 (–23,131,337). The Parent Company's cash and cash equivalents at year-end amounted to SEK 101,963,730 (28,603,699).

Proposed appropriation of earnings

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

SEK

Share premium reserve	235,844,614
Accumulated deficit	-80,546,687
Loss for the year	-28,763,809
Total	126,534,118

The Board proposes that the earnings be appropriated so that SEK 126,534,118 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 2015 to 31 December 2015.



The Group's future development

In 2015 Episurf Medical received market approval in the form of a CE mark for an additional two products, Episealer® Femoral Twin och Epiguide® MOS. The controlled product launch for the company's now four approved products Episealer® Trochlea Solo, Episealer® Condyle Solo, Episealer® Femoral Twin and Epiguide® MOS, is planned to continue during 2016. At the beginning of 2016 the company received CE mark approval for the fifth product, Epioscopy™ Damage Assessment Tool. The goals for 2016 are, among other things, to continue building up the sales organisation in Germany and the UK and to prepare a product portfolio ahead of a future launch in North America. Together, all of this could boost profitability in a longer perspective and lead to increased sales revenues for the company in 2016, but it will most likely also mean higher expenses for the company.

Episurf Medical's cash and cash equivalents at year-end amounted to SEK 104 million. Based on the current the operations, development pace and workforce, the Board of Directors and the CEO have assessed that the existing funds will cover the company's capital requirements during the next 12 months.

Guidelines for remuneration to senior executives

On 25 February 2015, the Board of Directors decided to appoint a remuneration committee that consists of Jeppe Magnusson, who is also chairman of the committee, Saeid Esmaeilzadeh and Thomas Nortoft.

The company's AGM on 6 May 2015 resolved to implement the following guidelines for remuneration to senior executives for the period until the 2016 AGM. Remuneration and terms of employment for senior executives, by which is meant the Chief Executive Officer, the Chief Financial Officer, the Deputy Chief Executive Officer, the Chief Marketing Officer and the Chief Quality Officer, 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 and there are no other agreements between the company and the CEO or senior executives that allow for benefits after employment has been terminated.

The employment contract for the company's CEO Rosie Cunningham Thomas is an indefinite duration contract effective 30 June 2015. Rosemary Cunningham Thomas receives a fixed monthly salary and customary pension provisions. The employment contract stipulates a mutual term of notice of six 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.

During the period from July to December 2015, the CEO received salary and remuneration of SEK 946,829 (0) and pension expenses for 2015 will be paid in an amount of SEK 137,064 (0). Salary and remuneration paid to the company's former CEO Nina Bake during the year amounted to SEK 977,920 (2,110,320) and pension expenses were paid in amount of SEK 181,680 (165,681).

Incentive program

In connection with the AGM on 31 March 2015, the Board decided to propose that the AGM approve the implementation of a combined bonus and incentive program. Under the program, which is open to all employees in the company, all employees will be offered a higher bonus of the amount

received is used to subscribe for shares in the company at market price. The incentive program was conditional on a resolution by the AGM to approve the issue of shares to the employees with deviation from the shareholders' pre-emptive rights. The AGM on 6 May 2015 resolved to implement the incentive program.

Related party transactions

Consulting fees of SEK 540,000 (810,000) were paid the shareholder and board member Leif Ryd during the period.

Serendipity Professionals AB has received total consulting fees of SEK 1,629,951 (180,000), of which SEK 662,875 referred to re-invoiced expenses, and Serendipity Communications AB has received total consulting fees of SEK 613,265 (210,500). Serendipity Professionals AB and Serendipity Communications AB are companies affiliated with Episurf Medical's largest shareholder, Serendipity Ixora AB.

Board fees to the chairman and other members of the Board were paid in a amount of SEK 100,000 to each, for a total of SEK 500,000 (500,000).

Significant risks and uncertainties

Clinical trials

Episurf Medical has been conducting a clinical trial in humans since 2012. If the study were to result in unforeseen or negative outcomes, this could have a negative impact on the company. This study is focused on implementation of tests on humans for Episealer® Condyle Solo, where the main study parameters are joint pain and function. If the study were to result in unforeseen or negative outcomes, this could have a negative impact on Episurf Medical.

Dependence on reimbursement systems

The opportunities for the company and its partners to successfully commercialise products, and the potential for future sales, will depend among other things on the existence and level of reimbursement for the company's products from insurance companies, government authorities and other payors for healthcare products and services. These reimbursement systems are complex and varying,

and as a rule it is the payors' ambition to regulate the prices of the company's products. Furthermore, how the product is classified internally by the payor is often decisive for the amount of reimbursement payable.

Regulatory approval

In order to market and sell medical devices, permits/approvals must be obtained and the products must be registered with the relevant authorities in each market. Episurf Medical cannot guarantee that such permits/approvals will be obtained to the extent necessary to achieve profitability or meet the company's future objectives. As a result of changes in the existing regulations or classifications, political decisions or changes in practice among public authorities, insurance companies and other decision-makers, reimbursement for Episurf Medical's future products may be lower than anticipated or may not be received, which would have a material negative impact on the Group's operations, earnings and financial position.

Risks related to possible future revenue

Episurf Medical's earnings are dependent among other things on the company's success in entering into additional agreements for distribution of the company's products. The opportunities to enter into such agreements are dependent among other things on Episurf Medical's credibility as a potential partner and the quality of the company's products. There is a risk that such agreements cannot be entered into, or can be only entered into on terms that are unfavourable for the company. To enter into such agreements, potential distributors in different markets and other collaboration partners, above all with regard to research and development, may require that additional studies be carried out on Episurf Medical's products, which could lead to delays and higher costs for the company. If Episurf Medical does not succeed at entering into agreements on terms that are favourable for the company, if such agreements lead to delays and higher costs, or if payment pursuant to the agreements is delayed or is not made, this could have a material negative impact on the Group's operations, earnings and financial

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position. Episurf Medical's earnings are also dependent on the company's ability to build up in-house sales organisations with direct sales capabilities, initially in the Nordic countries, the Benelux countries, Germany and the UK. If Episurf Medical does not succeed in building up an in-house sales organisation, the company could fail to generate sales revenue, in whole on in part, which could have a material negative impact on the Group's operations, earnings and financial position.

Market acceptance

Episurf Medical operates in a competitive industry and many other companies conduct R&D on medical devices, including ones that can, or may in the future, compete with the company's products and product candidates. In addition, R&D on products that do not compete directly with the company's products may replace all or parts of the company's product portfolio in the market, and consequently lead to lower demand for Episurf Medical's products. Episurf Medical operates in a market where many of the company's competitors have significantly greater financial resources than the company.

Furthermore, Episurf Medical's products employ new technology that has not been previously used in the company's intended application areas and must compete with more established treatments that are currently accepted as the industry standard. The opportunities for the company's products to compete are dependent on changes in the established practice in the medical profession. The opportunities for Episurf Medical to gain acceptance for its products in the medical profession and in the market are dependent among other things on the outcome of the controlled product launches that are currently underway. Although the products that have been launched have undergone both preclinical and clinical studies, the controlled product launch may not have a positive overall outcome. Moreover, negative events, in the controlled product launches or otherwise, caused by Episurf Medical's products or by incorrect handling of these, could have a negative impact on market acceptance. Even if Episurf Medical or its partners can prove that a product is safe and effective, market acceptance could be negatively affected.

If the company is not able to achieve a sufficient degree of market acceptance and effectively compete in the market, this could have a material negative impact on the Group's operations, earnings and financial position.

Rapid changes in the market for orthopaedic medical devices could make the company's products obsolete.

The market for medical devices is continuously evolving with regard to the existing technology, new technological advances and improvements in industrial knowhow, and such changes can take place rapidly. Consequently, Episurf Medical's successes will depend to a large extent on the company's ability to adapt to such external factors, to diversify the product portfolio and to develop new and competitively priced products that meet the requirements of ever-changing needs in the market. Furthermore, future technological advances may cause the company's currently or future planned products to lose their commercial value. If the company is not able to adapt to the technological advances, this could have a material negative impact on the Group's operations, earnings and financial position.

Patient damages

Patients who take part in the clinical studies and the controlled product launches that are conducted by the company may be negatively affected by the company's products or by incorrect handling of the company's products. Should such negative effects arise, this could cause the company's product development to be delayed or stopped, or could lead to liability for damages or other liability, which would have a material negative impact on the Group's operations, earnings and financial position.

Complex and varying changing requirements

In order to market medical device products, the company, its partners and suppliers must have, or be able to obtain, the relevant permits from government authorities for the different markets. Examples of these include CE marking in Europe and approval from the FDA (Food and Drug

Administration) for the US market. Rules, related among other things to preclinical and clinical trials and marketing of Episurf Medical's product portfolio are complex and change over time. In addition, the company has from time to time received development grants, and the reception of additional grants could be associated with special requirements. Furthermore, the company is subject to extensive other legislation and regulatory authority practice, and may in the future be subject to additional legislation and regulatory authority practice, including such that are related to public procurements. Changes in laws, rules or regulatory authority practice could increase Episurf Medical's expenses, or otherwise obstruct Episurf Medical's product development. Furthermore, the company could be imposed with sanctions if the company fails to comply with the above regulations. All of these factors could have a material negative impact on the Group's operations, earnings and financial position.

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 USA, 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 inventions 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 lifetime.

There is a risk that the existing and future product portfolio and other intellectual property rights that are held by the company will not provide adequate commercial protection. The technologies that Episurf Medical uses in its research, or that are included in the medical device products that Episurf Medical develops and commercialises, or intends to develop and commercialise, could infringe on patents that are owned or controlled by another party. Furthermore, a third party may have applied for a patent that covers the same product or technology as the company's.

If Episurf Medical is forced to initiate legal proceedings to determine who holds the commercial rights, the cost of such legal proceedings could be significant. The company may lose such legal disputes, which could cause the company to lose protection for, or the right to sell, any or all of the company's products, or force Episurf Medical to pay substantial damages.

Episurf Medical is also dependent on knowhow and trade secrets and the company strives to protect such information, among other things through confidentiality agreements with employees, consultants and collaboration partners. However, it is not possible to fully protect the company from unauthorised disclosure of information, which creates a risk that competitors could partake of and utilise the knowhow that has been developed by Episurf Medical.

If any of the above risks should arise, this could have a material negative impact on the Group's operations, earnings and financial position.

At present, Episurf Medical has a number of filed patent applications that are in different phases. The company cannot guarantee that all of these will result in approved patents. In total, Episurf Medical has around 80 patent applications under consideration in Europe and the USA.

Collaboration partners

Episurf Medical has a small organisation and the company therefore works with a number of different partners in order to maintain high flexibility and access to the right skills and expertise. Episurf Medical is dependent on continued close collaboration with current and future partners such as researchers, technical consultants, distributors, clinical trial leaders and suppliers for production. There are no guarantees the current and future partners will successfully meet their obligations or that partners with the right skills and expertise will be available, which could delay or obstruct development of the products. Because the company's products are customised, they are manufactured on demand in preparation for a specific surgical procedure. If the company is unable to deliver the product on time, the procedure may need to be rescheduled or cancelled, which could among

other things damage the company's reputation and lead to damage claims. Repeated failure to delivery products on time, whether the fault of the company or its partners or suppliers, could have a material negative impact on the Group's operations, 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 were to leave the company, it could delay or complicate the company's continued research, development and operations. Furthermore, the company is dependent on the ability to attract and retain qualified personnel. There is fierce competition for experienced manpower in the company's area of operation and many of Episurf Medical's competitors have significantly greater financial resources than the company, which could lead to an inability to recruit the necessary personnel, or force the company to recruit on unfavourable terms. If Episurf Medical is unable to recruit and retain key employees and other qualified personnel to the extent and on the terms necessary, this could have a material negative impact on the Group's operations, earnings and financial position. Moreover, there is a risk that poor decisions by the Board of Directors, executive management or key employees could have a negative impact on the company.

Financial risks

Through its operations, the Group is exposed to different types of financial risk, such as market risks, liquidity risks and credit risks. The market risks consist mainly of interest rate risk and foreign exchange risk. The company's Board of Directors has ultimate responsibility for exposure, management and monitoring of the Group's financial risks. 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 7,956,579, of which 1,761,333 were class A and 6,195,246 were class B shares. The total number of shares at year-end 2015 was 15,963,305, of which 3,470,769 were class A shares and 12,492,536 were class B shares. The total number of votes was 22,911,824.

When Michael McEwan left his position as CCO of Episurf Medical in August 2015, he surrendered, without compensation, 13,501 of the 16,877 class B shares that were issued to him by the decision of the 2015 Annual General Meeting (AGM). (The company intends to propose that the 2016 AGM resolve to cancel these 13,501 shares through reduction of the share capital). The number of shares outstanding at 31 December 2015 was thus 15,949,804 and the number of class B shares was 12,479,035.

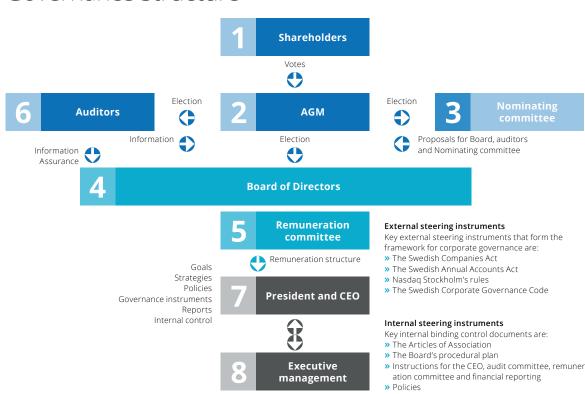
The share capital at 31 December 2015 amounted to SEK 4,788,991,50, with a quota value of SEK 0.30 per share. According to the Articles of Association, the share capital shall amount to no less than SEK 1,920,000 and no more than SEK 7,680,000, divided between no fewer than 6,400,000 shares and no more than 25,600,000 shares.

The number of shareholders at year-end was 1,940 (1,444). The ten largest shareholders in Episurf Medical in terms of voting power held shares corresponding to 53.3 per cent (48.9) of the share capital and 65.4 per cent (61.6) of the votes. The largest shareholder, Serendipity Ixora Fund AB, held shares corresponding to 17.7 per cent (17.2) of the share capital and 37.0 per cent (35.8) 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.

Governance structure



The company's corporate governance is regulated by the Articles of Association, the Swedish Companies Act, 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 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.

Share and shareholders

Episurf Medical's shares are issued in two classes, class A and 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

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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 2015 was 15,963,305, of which 3,470,769 were class A shares and 12,492,536 were class B shares.

The number of shareholders at year-end was 1,940 (1,444). The ten largest shareholders in Episurf Medical in terms of voting power held shares corresponding to 53.3 per cent (48.9) of the share capital and 65.4 per cent (61.6) of the votes. The largest shareholder, Serendipity Ixora Fund AB, held shares corresponding to 17.7 per cent (17.2) of the share capital and 37.0 per cent (35.8) of the votes. For further information about the share, shareholders and ownership structure, see pages 29-31 of the annual report.

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.

2015 AGM

The AGM on 6 may 2015 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.
- » To pay a fixed board fee of SEK 100,000 to each member of the Board, for a total of SEK 500,000. 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 Saeid Esmaeilzadeh, Leif Ryd, Thomas Nortoft, Jeppe Magnusson and Robert Charpentier as regular Board members for the period until the next AGM, Saeid Esmaeilzadeh was re-elected as Board Chairman.
- » To elect the auditing firm of KPMG AB as the company's independent auditor for the period until the end of the 2016 AGM, with Duane Swanson as the auditing firm's appointed Auditor in Charge.
- » To adopt the principles for appointment of the nominating committee ahead of the 2016 AGM in accordance with the proposal in the notice of meeting.
- » To adopt the guidelines for remuneration to senior executives in accordance with the proposal in the notice of meeting, to apply for the period until the 2016 AGM.
- » To implement an incentive program for senior executives and other employees in accordance with the proposal in the notice of meeting.

- » To carry out a private placement to Michael Edward McEwan of 16,877 class B shares with deviation from the shareholders' pre-emptive rights in accordance with the principles stated in the notice of meeting.
- » To authorise the Board of Directors, during the period until the next AGM, on one or several occasions, to decide on the issue of shares with our without preferential rights for the shareholders within the limits permitted by the Articles of Association, to be paid for in cash or in kind.

Extraordinary general meeting, August 2015

The extraordinary general meeting on 21 August 2015 resolved to approve a new issue of shares with preferential rights for the shareholders and a private placement of class B shares to the company's new CFO.

2016 AGM

The 2016 AGM will be held in Stockholm on 24 May 2016. The notice of meeting will be made public through a press release and announcements in Post och Inrikes Tidningar and Dagens Industri, as well as publication on Episurf Medical's website.

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

Members of the nominating committee ahead of the 2016 AGM

Saeid Esmaeilzadeh Chairman of Episurf Medical AB Ashkan Pouya Representing Serendipity Ixora AB Peter Ragnarsson Representing LMK Stiftelsen Björg Arnardóttir Representing Kaupthing HF

Ashkan Pouya has been appointed chairman of the nominating committee.

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fees. The 2015 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.
- » 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 ap-

propriate, 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 nominating committee's proposals are published in the notice of the AGM, on the company's website and at the AGM. No fees have been paid for work on the nominating committee.

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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 2015 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 four 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. Saeid Esmaeilzadeh is not deemed to be independent in relation to major shareholders as he himself is a major shareholder in the company (through direct holdings or via company). No 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.

Composition of the Board

Independent

					Meeting	From the	From share-
Name	Function	Born in	Elected in	Fees (SEK)	attendance	company	holders
Saeid Esmaeilzadeh	Board Chairman	1974	2008	100,000	9 of 9	Yes	No
Leif Ryd	Board member	1949	2008	100,000	9 of 9	No	Yes
Thomas Nortoft	Board member	1950	2010	100,000	9 of 9	Yes	Yes
Jeppe Magnusson	Board member	1952	2012	100,000	9 of 9	Yes	Yes
Robert Charpentier	Board member	1965	2014	100,000	9 of 9	Yes	Yes

Every year, the Board shall hold an inaugural meeting

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 May 2015. 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 entirely 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.

Word of the Board in 2015

The Board held nine meetings in 2015. The Board members' attendance is shown in the table below.

Each scheduled Board meeting followed an agenda and decision data was sent to the members of the Board ahead of each meeting. The CEO and certain other senior executives in the company have taken part in Board meetings in order to present reports. The Board has dealt with matters such as R&D, marketing plans and commercialisation of products, organisation, financial reporting and monitoring, financial position and investments.

In 2015 the Board devoted special attention to issues related to marketing and sales.

Remuneration to the Board

The nominating committee puts forward a proposal to the AGM regarding remuneration to the members of the Board.

The Board Chairman and members of the Board have been paid fees in accordance with the decision of the AGM. The Board Chairman and members of the Board have received Board fees of SEK 100,000 each, for a total of SEK 500,000 (500,000) for 2015. In 2015 Board member Leif Ryd was also paid SEK 540,000 in consulting fees.

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November

Scheduled Board meeting, budget/business plan for the coming year.

Scheduled Board meeting, discussion of interim report for January to June, Board evaluation, business strategy and organisation.

Scheduled Board meeting, capital procurement, strategies for the change of CEO. Decision to call an extraordinary general meeting.

Scheduled Board meeting, decision on change of CEO, strategies for the change of CEO.

Board meetings in 2015

February

Scheduled Board meeting, year-end report, finalised budget. Change in senior management.

Decisions regarding the annual report, notice of the AGM, members of the foreign company boards, etc.

Scheduled Board meeting, interim report for January to March.

Inaugural meeting; decision on authorised signatories, adoption of instructions and policies, appointment of remuneration committee, appointment of board representative to the nominating committee, decision on the time and location of the coming scheduled Board meetings, the AGM and reporting dates.

Extra Board meeting, decision on allocation of shares according to the decision of the AGM.

The fixed items on the agenda of scheduled Board meetings have included the operations and financial results of the company and the subsidiaries, the CEO's situation report, sales and marketing strategy, feedback from the remuneration committee, and other pertinent projects and matters.

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Remuneration committee

At 25 February 2015, Episurf Medical had appointed a remuneration committee.

Remuneration committee	No. of meetings
Jeppe Magnusson, Chairman	1
Saeid Esmaeilzadeh	1
Thomas Nortoft	1

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.

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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. The 2015 AGM appointed the auditing firm of KPMG AB to serve as the company auditor until the end of the 2016 AGM, with Duane Swanson as the auditing firm's appointed Auditor in Charge.

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.

Rosemary Cunningham Thomas is Episurf Medical's CEO since June 2015. Rosemary Cunningham Thomas has a bachelor's degree in Pharmacology from the University of Science in Philadelphia and has studied economy at the University of Pennsylvania. She has broad experience from managing companies through their growth phase to becoming market-leading actors with good profitability.

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 2015 the executive management consisted of Nina Bake (CEO), Lena Lones (CFO) and Jeanette Spångberg (COO).

Several changes were made in the executive management during 2015 in order to strengthen the company's focus on commercial expansion. Michael McEwan, Chief Commercial Officer (CCO) was a member of the executive management from February to September, and at the end of June Rosemary Cunningham Thomas replaced Nina Bake as CEO of the company. Pål Ryfors took up duties as the new CFO in December.

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Remuneration to the CEO and management

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The company's AGM on 6 May 2015 resolved to implement the following guidelines for remuneration to senior executives for the period until the 2016 AGM. Remuneration and terms of employment for senior executives, by which is meant the Chief Executive Officer, the Chief Financial Officer and the Chief Operating Officer, 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 consisting of Jeppe Magnusson, who is also chairman of the committee, Saeid Esmaeilzadeh and Thomas Nortoft.

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

Incentive program

The Board meeting on 31 March 2015 decided to propose to the AGM the implementation of a combined bonus and incentive program. Under the program, which is open to all employees in the company, all employees will be offered a higher bonus of the amount received is used to subscribe for shares in the company at market price. The incentive program was conditional on a resolution by the AGM to approve the issue of shares to the employees with deviation from the shareholders' pre-emptive rights. The AGM on 6 May 2015 resolved to implement the incentive program.

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. The Parent Company's and the subsidiaries' assets, liabilities, valuations, revenue, expenses, cash flows and application of accounting policies is analysed continuously, among other things in the reporting process. 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

Monitoring is carried out at all levels in the company. The Board of Directors monitors internal control to ensure that shortcomings are corrected and that good ideas are realised, among other things by evaluating the executive management's information.

Board of Directors

According to the Articles of Association, Episurf Medical's Board of Directors shall consist of at least three and at most eight members, with up to two deputies. The company's Board of Directors currently consists of five members, including the Chairman, All Board members are elected to serve until the end of the next AGM. Below is a presentation of the Board members with information about their year of birth, education, year of election to the Board, other current positions and shareholdings. Assignments in the Group are not stated. Shareholdings in the company include own direct and indirect holdings and related party holdings at 31 December 2015.

[46]



Saeid Esmaeilzadeh Board Chairman since 2009 Shares 2,822,563 class A share (via company)

Education and experience: Saeid is an Adjunct Professor of Materials Chemistry at Stockholm University. He received his Ph.D. from the same university in 2000 and in 2002 was appointed as Sweden's youngest Associate Professor. He has received numerous awards and honours for his research and his contributions as an entrepreneur. Saeid is the CEO of Serendipity Innovations AB and former CEO of Diamorph AB. Saeid is a serial entrepreneur and has been involved in establishing several research-based

Current positions: Chairman of Xbrane Bioscience AB, Serendipity Ixora AB, Premune AB (publ) and Swecure AB (publ). Board member of Diamorph AB (publ), Sdiptech AB (publ), Serendipity Group AB, Irras AB and Nextseal AB. Deputy board member of Serendip Invest AB, Serendipity Ventures AB, Serendipity Innovations AB, VZL Vilande AB, Sprof AB, Leonova Consulting AB, OrganoClick AB, Swecure Europe AB, Auremune AB, Premune IPR AB, Swecure IPR AB, DynaSeal LCT AB and Decicure AB.

Independence: Saeid is independent from the company and its management, but not from the company's largest shareholders.



Robert Charpentier Board member since 2014 Shares 5.747 class A shares **Born in 1965**

Education and experience: Robert has a Master's degree from the Swedish School of Economics in Helsinki. He has extensive experience on boards and in senior positions at Swedish and international listed companies. Robert has previously held positions as CEO of Kaupthing Bank Sweden, Executive Vice President of Swedbank Group and as director at Goldman Sachs International, London.

Current positions: Chairman of As Oy Helsingin Ratakatu 27, Kvigos AB, Vator Securities AB, Snellman Properties AB, Winston AB, Individia Group AB, MA2 AB, Snellman Properties Merikatu Oy, Snellman Properties Ruoholahdenkatu Oy, Snellman LKV Oy, Shark House Oy, Snellman Properties Ratakatu Oy, Aage Skouboes Vej 2 A/S and Vingen Ejendomme ApS. Board member of AllTele Allmänna Svenska Telefonaktiebolaget (publ), Gunillaklockan Fastigheter AB, Let Us Care AB and OrganoWood AB. Deputy board member of Snellman Properties

Independence: Robert is independent from the company and its management and from the company's largest shareholders.

Born in 1974





Jeppe Magnusson Board member since 2012 Shares 23.650 class B shares (directly and via company)

Born in 1952

Education and experience: Jeppe has a Ph.D. in Chemical Reaction Engineering from Chalmers University in Gothenburg and has been a partner at ISEA, Industry Senior Advisors, since 2009. Jeppe has over thirty years of industry experience from leading positions in international organisations such as Nobel Industries, Union Carbide, Mölnlycke, SCA Hygiene Products and Nobel Biocare, where he was responsible for research and development, technology and innovation, IP, clinical research and marketing of new products.

Current positions: Board member of Auremune AB, Premune AB (publ), Premune IPR AB and Swecure AB

Independence: Jeppe is independent from the company and its management and from the company's largest shareholders.



Thomas Nortoft Board member since 2010 Shares 10,258 class B shares **Born in 1950**

Education and experience: Thomas has an MBA from Gothenburg University. He was previously CEO of Älvsborg RoRo AB and has over ten years of experience from the management team of Nobel Biocare with different areas of responsibility, including Europe and Asia, the dental implants business area, business development and President U.S. and Canada. Thomas has also worked as a management consultant for Indevo and ten years at Mölnlycke AB (SCA) in accounting and finance.

Current positions: Chairman of Integrum and board partner of Nortoft Aktiebolag.

Independence: Thomas is independent from the company and its management and from the company's largest shareholders.



Leif Ryd Board member since 2009 Shares 255,168 class A shares 131,454 class B shares Born in 1949

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

Current positions: Chairman of Aktiebolaget Gile Medicinkonsult.

Independence: Leif is independent from the company's largest shareholders, but not from the company and its management.



Auditors The 2015 AGM elected the auditing firm of KPMG AB as the company's independent auditor to serve until the end of the 2016 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: Tegelbacken 4, SE-111 52 Stockholm, Sweden.

Changes in the Board and management during the year and after the end of the year

No changes took place in the Board during the year. The executive management changed during the year when Rosemary Cunningham Thomas replaced Nina Bake as CEO in June and when Michael McEwan left his position in September. Pål Ryfors took up duties as the new CFO in December.

Executive management



Rosemary Cunningham Thomas CEO since 2015

Shares -

Born in 1963

Education and experience: Rosemary Cunningham Thomas has a Bachelor's degree in Pharmacology from the University of Science in Philadelphia and has studied economy at the University of Pennsylvania. She has broad experience from managing companies through their growth phase to becoming market-leading actors with good profitability. Rosemary has among other things been CEO of UK-based ToHealth Ltd., interim CEO of Freehand 2010 Ltd. and General Manager & President Europe for Galil Medical. Prior to that, she was sales and marketing director for CR Bard Inc., which is listed on the New York Stock Exchange. Rosemary has also held several key positions at Smiths Industries Med Systems (now Smiths Medical), for example as business area manager, sales and marketing manager and responsible for commercial partner development projects.

Current positions: Member of Commercial Advisory Board in leso Digital Health.



Pål Ryfors, CFO since 2015

Shares 16,393 class B shares

Born in 1983

Education and experience: Pål has a Bachelor's degree 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 with some 350 employees, 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, which he joined after holding several leading positions in the restructuring of the Swedish operations of Kaupthing Bank.

Current positions: -



Jeanette Spångberg COO since 2011

Shares 1,211 class B shares

Born in 1973

Education and experience: Jeanette has a Bachelor of Science in Construction Engineering, Information Technology and Environment from the Royal Institute of Technology (KTH). She has long experience in customised implant production, production logistics, product and production development from Nobel Biocare, where she worked as Production Manager, Technical Manager and Global Engineering Manager. Jeanette has also worked extensively with quality management systems, among other things for ISO 9001 and ISO 1348 certification, as well as automation and system support for customised production. Employed as COO since 2011.

Current positions: -

Five year overview – Group

Consolidated financial statements were prepared for the first time in connection with the 2013 annual report, and group conditions arose first when the subsidiaries were registered in mid-March 2013. There were no significant operations in the subsidiaries in the first half of 2013.

SEK 000s	Jan-Dec 2015	Jan-Dec 2014	Jan-Dec 2013	Jan-Dec 2012	Jan-Dec 2011
INCOME STATEMENT					
Operating income	6,645	2,339	1,696	-	-
Operating expenses	-50,654	-35,600	-24,976	-16,303	-10,160
Operating loss	-44,009	-33,261	-23,280	-16,303	-10,160
Financial items	34	347	423	533	523
Loss after financial items	-43,975	-32,914	-22,857	-15,770	-9,637
Income tax expense	_	_	_	_	-
Loss for the year	-43,975	-32,914	-22,857	-15,770	-9,637
ASSETS					
Intangible assets	11,046	5,895	4,694	2,526	1,627
Property, plant and equipment	424	427	519	121	100
Other current assets	2,769	2,426	2,341	2,190	865
Cash and bank balances	103,961	34,490	68,869	23,075	39,613
Total assets	118,200	43,238	76,423	27,912	42,205
EQUITY AND LIABILITIES					
Equity	109,934	38,849	71,614	24,392	40,161
Current liabilities	8,266	4,389	4,809	3,520	2,044
Total equity and liabilities	118,200	43,238	76,423	27,912	42,205

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Five-year overview – Group, cont'd.

SEK 000s	Jan-Dec 2015	Jan-Dec 2014	Jan-Dec 2013	Jan-Dec 2012	Jan-Dec 2011
CASH FLOW STATEMENT					
Cash flow from operating activities	-38,039	-31,659	-20,643	-15,045	-9,092
Cash flow from investing activities	-7,376	-2,870	-3,642	-1,493	-1,533
Cash flow from financing activities	114,886	150	70,078	-	43,222
Cash flow for the year	69,471	-34,379	45,793	-16,538	32,597
KEY RATIOS					
Share price at year-end	17.5	35.7	65.5	24.4	22.4
Earnings per share (weighted average)	-3.52	-2.98	-2.09	-2.46	-2.08
Equity per share	6.89	4.88	9.00	3.81	6.27
Number of shares at end of year	15,963,305	7,956,579	7,953,986	6,400,000	6,400,000
Average number of shares during the year	12,504,417	11,059,418 ¹	10,919,929 ¹	6,400,0001	4,628,6941
Equity ratio, %	93.00	89.80	93.70	87.40	95.90
Number of employees at the end of the year	18	14	9	6	4
Cash and cash equivalents at the end of year	103,961	34,490	68,869	23,075	39,613
Cash flow for the year	69,471	-34,379	45,793	-16,538	32,597
Investments in intangible assets	7,248	2,831	3,174	1,446	1,441
Investments in property, plant and equipment	129	39	468	47	92

¹⁾ Historical figures restated in accordance with IAS 33.

Consolidated income statement

Consolidated statement of comprehensive income

SEK	Note	Inn Doc 2015	Inn Doc 2014
SEK	Note	Jan-Dec 2015	Jan-Dec 2014
Operating income			
Net sales		1,016,462	173,026
Other operating income	6	5,628,598	2,166,468
Total operating income		6,645,060	2,339,494
Operating expenses			
Other external expenses	8	-21,584,339	-21,302,806
Personnel costs	9	-26,834,214	-12,536,904
Amortisation of intangible assets and			
depreciation of property, plant and equipment		-2,235,026	-1,761,043
Total operating expenses		-50,653,579	-35,600,753
Operating loss		-44,008,519	-33,261,259
Financial income	7	34,544	353,322
Financial expenses	7	-687	-6,484
Loss after financial items		-43,974,662	-32,914,421
Loss after tax		-43,974,662	-32,914,421
Income tax expense	10	-	
Loss for the year		-43,974,662	-32,914,421

SEK	Note	Jan-Dec 2015	Jan-Dec 2014
Loss for the year		-43,974,662	-32,914,421
Other comprehensive income for the year: Other comprehensive income for the year,			
net of tax		173,229	_
Total comprehensive income for the year		-43,801,433	-32,914,421
The year's loss and comprehensive income attributable to			
Owners of the parent		-43,801,433	-32,914,421
Earnings per share, basic and diluted		-3.52	-2.98
Average number of shares		12,504,417	11,059,418¹

¹⁾ Historical figures restated in accordance with IAS 33.

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Consolidated balance sheet

SEK	Note	31 Dec 2015	31 Dec 2014
ASSETS			
Non-current assets			
Capitalised expenses		4,660,637	483,702
Patents	11	6,385,717	5,411,307
Total intangible assets		11,046,354	5,895,009
Equipment and tools	12	423,838	426,682
Total property, plant and equipment		423,838	426,682
Total non-current assets		11,470,192	6,321,691
Current assets			
Inventories	15	1,154,578	1,473,664
Trade receivables	14	199,864	24,344
Other receivables		869,741	468,558
Deferred expenses and accrued income	16	545,064	460,331
Cash and cash equivalents		103,960,776	34,489,799
Total current assets		106,730,023	36,916,696
TOTAL ASSETS		118,200,215	43,238,387
			i

SEK	Note	31 Dec 2015	31 Dec 2014
EQUITY			
Equity attributable to owners of the parent			
Share capital	17	4,788,991	2,386,974
Other contributed capital	17	237,044,614	124,560,235
Reserves		173,229	-
Accumulated deficit incl. loss for the year		-132,072,295	-88,097,632
Total equity		109,934,539	38,849,577
LIABILITIES			
Current liabilities			
Trade payables		1,787,912	1,089,888
Other liabilities	18	1,745,361	678,925
Accrued expenses and deferred income	19	4,732,403	2,619,997
Total current liabilities		8,265,676	4,388,810
TOTAL EQUITY AND LIABILITIES		118,200,215	43,238,387
Pledged assets and contingent liabilities			
Pledged assets		None	None
Contingent liabilities		None	None

[53]

Consolidated statement of changes in equity

SEK	Share capital	Other contributed capital	Reserves	Accumulated deficit incl. loss for the year	Total equity
Balance at 1 January 2014	2,386,196	124,410,878	_	-55,183,211	71,613,861
Comprehensive income	2,360,130	124,410,070	_	-33,103,211	71,015,001
Loss for the year				-32,914,421	-32,914,421
Other comprehensive income				32,317,721	32,314,421
No items to report					
Total comprehensive income	-	-	-	-32,914,421	-32,914,421
Transactions with owners					
New share issue, net after expenses	778	149,357	-	-	150,135
Total transactions with owners	778	149,357	-	-	150,135
Balance at 31 December 2014	2,386,974	124,560,235	-	-88,097,632	38,849,575
Balance at 1 January 2015	2,386,974	124,560,235	_	-88,097,632	38,849,575
Comprehensive income					
Loss for the year	-	-	173,229	-43,974,663	-43,801,434
Other comprehensive income					
No items to report					
Total comprehensive income			173,229	-43,974,663	-43,801,434
Transactions with owners					
New share issue, net after expenses	2,402,017	112,484,379	-	-	114,886,396
Total transactions with owners	2,402,017	112,484,379	-	-	114,886,396
Balance at 31 December 2015	4,788,991	237,044,614	173,229	-132,072,295	109,934,539

Consolidated cash flow statement

SEK	Jan-Dec 2015	Jan-Dec 2014
Cash flow from operating activities		
Operating loss	-44,008,519	-33,261,259
Adjustments for non-cash items		
Add-back of amortisation and depreciation	2,235,026	1,761,043
Interest received	34,544	353,322
Interest paid	-687	-6,484
Interest paid	-	_
Cash flow from operating activities before changes in working capital	-41,739,636	-31,153,378
Changes in working capital		
Change in inventory and work in progress	319,086	-934,184
Change in trade receivables	-175,520	-8,927
Change in other current receivables	-493,057	857,027
Change in other current liabilities	3,352,071	470,793
Change in trade payables	698,024	-890,757
Total changes in working capital	3,700,604	-506,048
Cash flow from operating activities	-38,039,032	-31,659,426

SEK	Jan-Dec 2015	Jan-Dec 2014
Cash flow from investing activities		
Investments in intangible assets	-7,247,777	-2,830,838
Investments in property, plant and equipment	-128,610	-38,699
Cash flow from investing activities	-7,376,387	-2,869,537
Cash flow from financing activities		
New share issue	114,886,396	150,135
Cash flow from financing activities	114,886,396	150,135
Cash flow for the period	69,470,977	-34,378,828
Cash and cash equivalents at the beginning of the year	34,489,799	68,868,627
Cash and cash equivalents at the end of the year	103,960,776	34,489,799

Parent Company income statement

Parent Company statement of comprehensive income

SEK	Note	Jan-Dec 2015	Jan-Dec 2014
Operating income			
Net sales	6	754,609	195,978
Other operating income	6	5,627,648	2,166,468
Total operating income		6,382,257	2,362,446
Operating expenses			
Other external expenses	8	-12,949,289	-16,537,846
Personnel costs	9	-14,968,281	-9,401,693
Amortisation of intangible assets and depreciation of property, plant and equipment		-589,997	-126,730
Total operating expenses		-28,507,567	-26,066,269
Operating loss		-22,125,310	-23,703,823
Interest income and similar profit/loss items	7	415,906	577,725
Interest expenses and similar profit/loss items	7	-405	-5,239
Loss after financial items		-21,709,809	-23,131,337
Loss before appropriations and tax		-21,709,809	-23,131,337
Appropriations			
Group contributions paid		-7,054,000	-3,446,000
Loss before tax		-28,763,809	-26,577,337
Tax on loss for the year	10	-	
Loss for the year		-28,763,809	-26,577,337

SEK	Note	Jan-Dec 2015	Jan-Dec 2014
Loss for the year		-28,763,809	-26,577,337
Other comprehensive income:			
Other comprehensive income, net of tax		-	-
Total comprehensive income		-28,763,809	-26,577,337

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Parent Company balance sheet

SEK	Note	31 Dec 2015	31 Dec 2014
ASSETS			
Non-current assets			
Intangible assets			
Capitalised expenses	15	4,660,637	483,702
Patents	11	-	_
Total intangible assets		4,660,637	483,702
Property, plant and equipment			
Equipment	12	281,547	408,745
Total property, plant and equipment		281,547	408,745
Financial assets			
Shares in group companies	13	16,128,375	6 100 000
Non-current receivables from group companies		11,740,509	12 051 689
Total financial assets		27,868,884	18,151,689
Total non-current assets		32,811,068	19,044,136
Current assets			
Other receivables		356,533	233,043
Deferred expenses and accrued income	16	277,319	395,037
		633,852	628,080
Cash and bank balances		101,963,730	28,603,699
Total current assets		102,597,582	29,231,779
TOTAL ASSETS		135,408,650	48,275,915

SEK	Note	31 Dec 2015	31 Dec 2014
EQUITY			
Equity			
Restricted equity			
Share capital	17	4,788,991	2,386,974
Total restricted equity		4,788,991	2,386,974
Unrestricted equity			
Share premium reserve	17	235,844,614	123,360,235
Accumulated deficit		-80,546,687	-53,969,350
Loss for the period		-28,763,809	-26,577,337
Total unrestricted equity		126,534,118	42,813,548
Total equity		131,323,109	45,200,522
Current liabilities			
Trade payables		640,962	458,247
Other liabilities	18	556,315	394,728
Accrued expenses and deferred income	19	2,888,264	2,222,418
Total current liabilities		4,085,541	3,075,393
TOTAL EQUITY AND LIABILITIES		135,408,650	48,275,915
Pledged assets		None	None
Contingent liabilities		None	None

Parent Company statement of changes in equity

		Share premium			
SEK	Share capital	reserve	Accumulated deficit	Loss for the year	Total
Balance at 1 January 2014	2,386,196	123,210,878	-31,126,515	-22,842,835	71,627,724
Comprehensive income					
Loss for the year				-26,577,337	-26,577,337
Appropriation of loss according to decision of the AGM					
Loss carried forward			-22,842,835	22,842,835	-
Other comprehensive income			-	-	-
Total comprehensive income			-22 842 835	-3 734 502	-26 577 337
Transactions with owners					
New share issue, net after expenses	778	149,357			150,135
Total transactions with owners	778	149,357			150,135
Balance at 31 December 2014	2,386,974	123,360,235	-53,969,350	-26,577,337	45,200,522
Balance at 1 January 2015	2,386,974	123,360,235	-53,969,350	-26,577,337	45,200,522
Comprehensive income					
Loss for the year				-28,763,809	-28,763,809
Appropriation of loss according to decision of the AGM					
Loss carried forward			-26,577,337	26,577,337	-
Other comprehensive income			_	-	-
Total comprehensive income			-26 577 337	-2 186 472	-28 763 809
Transactions with owners					
New share issue, net after expenses	2,402,017	112,484,379			114,886,396
Total transactions with owners	2,402,017	112,484,379			114,886,396
Balance at 31 December 2015	4,788,991	235,844,614	-80,546,687	-28,763,809	131,323,109

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SEK	Jan-Dec 2015	Jan-Dec 2014
Cash flow from operating activities		
Operating loss	-22,125,310	-23,703,823
Adjustments for non-cash items		
Provisions, no effect on cash flow	-6,464,003	-3,319,270
Interest received	415,906	577,725
Interest paid	-405	-5,239
Cash flow from operating activities before changes in working capital	-28,173,812	-26,450,607
Changes in working capital		
Change in other current receivables	-5,779	927,998
Change in current liabilities	857,699	-118,555
Change in trade payables	182,715	-1,433,353
Total changes in working capital	1,034,635	-623,910
Cash flow from operating activities	-27,139,177	-27,074,517

SEK	Jan-Dec 2015	Jan-Dec 2014
Cash flow from investing activities		
Investments in intangible assets	-4,643,111	-483,702
Investments in/sales of property, plant and equipment	3,378	-16,274
Change in financial assets	-9,747,455	-12,656,617
Cash flow from investing activities	-14,387,188	-13,156,593
Cash flow from financing activities		
New share issue	114,886,396	150,135
Cash flow from financing activities	114,886,396	150,135
Cash flow for the year	73,360,031	-40,080,975
Cash and cash equivalents at beginning of year	28,603,699	68,684,673
Cash and cash equivalents at end of year	101,963,730	28,603,698

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Accounting policies and notes

Note

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 centres 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 Stora Skuggans väg 11, Stockholm, Sweden.

The consolidated financial statements and annual report were approved by the Board of Directors for publication on 20 April 2016.

All amounts are presented in SEK unless otherwise stated. Information in parentheses refers to the previous year.

Note

Significant accounting policies

2.1 Basis of presentation

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, and the Swedish Annual Accounts Act.

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.

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

At the time of preparation of the consolidated financial statements at 31 December 2015, 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 1 January 2015.

IFRS 16 "Leases"

A new standard for accounting for leases. For lessees, the classification according to IAS 17 as operating or financial leases is replaced by a model in which assets and liabilities for all leases are recognised in the balance sheet. The exceptions are leases where the underlying asset has a low value or leases that have a term of 12 months of less. In the income statement, depreciation is recognised separately from interest expenses attributable to the lease liability. There are assessed to be no major changes for lessors and the rules in IAS 17 are substantially unchanged with the exception of additional disclosure requirements. IFRS 16 is mandatorily effective for annual periods beginning on or after 1 January 2019. The EU has not yet set any date for approval.

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 och instrument's cash flow characteristics. The standard is effective for annual periods beginning on or after 1 January 2018. The Group has not yet evaluated the effects of the application of this standard.

[59]

IFRS 10 "Consolidated Financial Statements"

IFRS 10 is based on already existing standards for defining control for the purposes of presenting consolidated financial statements. The standard provides additional guidance for determining when the company has control over another entity.

IFRS 12 "Disclosure of Interests in Other Companies"

IFRS 12 contains disclosure requirements for all types of interests in other companies, such as subsidiaries, joint arrangements, associates and unconsolidated structured entities.

IFRS 15 "Revenue from Contracts with Customers"

IFRS 15 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". IFRS 15 is effective for annual periods beginning on or after 1 January 2017. The Group has not yet evaluated the effects of application of this standard.

No other IFRSs or IFRIC interpretations that are not yet effective are expected to have any material impact on the Group.

2.2 Scope of consolidation

Subsidiaries

Subsidiaries are all companies in which the Group directly or indirectly has the power to govern the financial and operating policies, generally accompanying a shareholding of more than one half of the voting rights or where the Group has sole control by virtue of an agreement with other investors. Subsidiaries are consolidated without non-controlling interests 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 in full. 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 and the Germany and English subsidiaries were formed in 2015.

Segment information

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker. The chief operating decision-maker is the function responsible for allocating resources and assessing the performance of the operating segments. In the Group, this function has been identified as the Board of Directors together with the CEO. At present, operations are monitored based on the Group as a whole, for which reason information is provided for one segment.

2.4 **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 functional currency of the Group is Swedish kronor (SEK), which is also the functional and presentation currency of the Parent Company and the subsidiaries.

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 2.5

Patents

Acquired 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.

At the end of the fourth quarter of 2014, the company determined that all of the above criteria had now been met, for which reason development expenses are capitalised as of 1 October 2014.

The company has started to amortise 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.

2.6 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, 5 years

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.

2.7 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.

2.8 Financial instruments

The Group classifies its financial assets and liabilities in the following categories: financial assets and liabilities at fair value through profit or loss, loans and receivables, available-for-sale financial assets and other financial liabilities. The classification depends on the purpose for which the financial asset was acquired. Management determines the classification on initial recognition and reviews this decision at each reporting date. At present there are only trade and other receivables, cash and cash equivalents, and trade and other payables.

Loans and receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted on an active market. They are included in current assets with the exception of amounts that are expected to be recovered more than 12 months after the balance sheet date, which are classified as non-current assets. Loans and receivables are recognised in trade receivables, other receivables and other non-current receivables in the balance sheet. Cash and cash equivalents are also included in this category. Impairment losses on trade payables are recognised in other external expenses.

Other financial liabilities

At present, the Group has only trade and other payables, which are classified as other financial assets. See also description of the accounting policies in section 2.13 below.

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. Inventories consist mainly of cables and other tools that are used for the company's services. 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.

2.10 Trade receivables

Trade receivables are initially recognised at fair value and are subsequently measured at amortised cost using the effective interest method less provisions for impairment. A provision for impairment of trade receivables is established when there is objective evidence that the Group will not be able to collect all amounts due according to the original terms of the receivables. Significant financial difficulties of the debtor, probability that the debtor will enter bankruptcy or financial reorganisation, and default or delinquency in payments (more than 60 days overdue) are considered indicators that the trade receivable is impaired The amount of the provision is the difference between the assets carrying amount and the present value of estimated future cash flows, discounted by the original effective interest rate. Both losses on trade receivables and recovery of amounts previously written off are recognised in selling expenses in the income statement.

The carrying amount of trade receivables, after impairment, is assumed to correspond to fair value, since this item is of a current nature.

These amounts are not discounted, due to their short maturities.

2.11 Cash and cash equivalents

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

2.12 Share capital

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

2.13 Trade payables

Trade payables are initially recognised at fair value and subsequently at amortised using the effective interest rate method. The carrying amount of trade payables is assumed to correspond to fair value, since this item is of a current nature.

These amounts are not discounted, due to their short maturities.

2.14 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.

Deferred tax liabilities arise on taxable temporary differences arising from investments in subsidiaries, except for deferred income tax liabilities where the timing of the reversal of the temporary difference is controlled by the Group and it is probable that the temporary difference will not reverse in the foreseeable future

2.15 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.

Share-based payment

The AGM on 6 May 2015 resolved to implement an incentive program for all employees. Under the incentive program, an employee can choose to subscribe for class B shares in the company instead of receiving a cash bonus. An employee who is entitled to a bonus in excess of basic salary, if awarded a bonus for a specific financial year, can instead of receiving a

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cash amount equal to the awarded bonus choose to receive double the bonus amount, provided that the employee uses the received amount to subscribe for shares in the company. For further information about this employee share option program, see Note 17.

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.

2.16 Provisions

Provisions are recognised when the Group has a legal or constructive obligation as a result of past events, it is probable that an outflow of resources will be required to settle the obligation and the amount has been reliably estimated. No provisions are made for future operating losses.

Provisions are measured at the present value of the expenditure expected to be required to settle the obligation using a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the obligation. The increase in the provision due to passage of time is recognised in interest expenses.

The Group recognises no provisions at present, but in pace with growth in sales, an assessment of warrantee commitments, among other things, will be taken into account.

2.17 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. In the future the Group may also sell other externally developed medical device products on a license basis.

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. The Group recognises revenue when the amount can be reliably estimated and it is probable the economic benefits associated with the transaction will fall to the company. This corresponds to the date when the goods were delivered to the customer.

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.

2.18 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.

2.19 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.

2.20 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.

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 affect 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 as an increase in the investment in the subsidiary.

Note

Financial risk management

3.1 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.

a) Market risk

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.

b) Credit risk

Credit risk is managed at the group level. Credit risk arises through cash and cash equivalents, deposits in banks and financial institutions and credit exposures to the Group's customers, including outstanding receivables and contractual transactions.

The maximum credit exposure consists of the book value of the exposed assets. At present the Group's credit risk is assessed to be limited, since most of the financial assets consist of cash and cash equivalents in major Swedish credit institutions.

c) Liquidity risk

At 31 December 2015 the Group had liquidity of SEK 103,961 thousand (34,489).

Liquidity risk for the coming year is limited, since the company's liquidity with the current burn rate will last for the coming 12-month period.

Future undiscounted cash flows correspond to the book values of the liabilities. There were no interest-bearing liabilities at 31 December 2015.

3.2 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

The Group is entirely funded through equity. The equity ratio at 31 December 2015 was 93.0 per cent (89.8).

3.3 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

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. In 2015 the company's third product, Episealer® Femoral Twin, and fourth product, Epiguide® MOS, received approval for sale on the market.

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 2.5 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 four 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 carryforwards

Every year, the Group examines whether there is any indication of impairment of deferred tax assets relating to tax loss carryforwards. Furthermore, the Group examines the opportunities to capitalise new deferred tax assets with respect to the year's tax loss carryforwards, 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. Note 10 shows that unvalued loss carryforwards at 31 December 2015 amounted to SEK 109,866 thousand (81,109). At 31December 2015 the Group had loss carryforwards amounting to SEK 131,326 thousand (87,417) that had not been included in calculation of the deferred tax asset.

Note

Segment information

Management determines the operating segments based on the information that is discussed and dealt with by the Board of Directors together with the CEO and is used to make strategic decision. 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 1,016,462 (17,026) refer primarily to sales of the Episurf products Episealer® Condyle Solo, Episealer® Trochlea Solo and Episealer® Femoral Twin. The Parent Company's net sales of SEK 754,609 (195,978) refer to intra-group sales.

Group	2015	2014
Government grants received	949,104	1,692,450
Capitalised development expenditure	4,643,111	483,702
Other	36,383	-9,684
Total other operating income	5,628,598	2,166,468

[65]

Parent Company	2015	2014
Government grants received	949,104	1,692,450
Capitalised development expenditure	4,643,111	483,702
Other	35,433	-9,684
Total other operating income	5,627,648	2,166,468

Note

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Financial income and expenses

The year's financial income and expenses consist of interest income and interest expenses. The year's interest income is attributable to interest from credit institutions.

Note

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 else is defined as other assignments.

Group	2015	2014
	KPMG	E&Y
Audit assignments	290,000	476,915
Other audit assignments	-	100,500
Tax advice	-	3,000
Other advisory services	35,000	50,000
Total	325,000	455,500

Parent Company	2015	2014
	KPMG	E&Y
Audit assignments	290,000	371,915
Other audit assignments	-	100,500
Tax advice	-	3,000
Other advisory services	35,000	50,000
Total	325,000	476,915

Note

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

Personnel costs

Group	2015	2014
Remuneration		
Salary and other remuneration	18,984,352	8,451,653
Social security expenses	4,679,813	2,527,178
Pension expenses – defined contribution plans	1,240,645	787,154
Other	1,929,404	770,919
Total	26,834,214	12,536,904

Parent Company	2015	2014
Remuneration		
Salary and other remuneration	9,586,049	6,461,895
Social security expenses	2,621,269	1,986,722
Pension expenses – defined contribution plans	706,992	548,283
Other	2,053,971	404,793
Total	14,968,281	9,401,693

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

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

Average number of employees

	2015		201	14
Group and Parent Company	Average no. of employees	Of whom, men	Average no. of employees	Of whom, men
Group	17	10	11	7
Parent Company	10	4	8	4

Gender distribution of Board members and other senior executives

	2015		201	14
Group and Parent Company	No. on balance sheet date	Of whom, men	No. on balance sheet date	Of whom, men
Board members	5	5	5	5
CEO and other senior executives	4	1	6	3
Total Group and Parent Company*	8	5	10	7

^{*} In 2014 Leif Ryd was both a member of the Board and, on the balance sheet date, a senior executive. In the total he is counted only once.

Note

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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	2015	2014
Profit before tax	-43,974,662	-32,914,421
Income tax calculated at the Group's applicable tax rate, 22%	9,674,426	7,241,173
Income that is exempt from taxation	701	872
Expenses not deductible for tax purposes	-65,842	-101,794
The year's tax loss carryforward not recognised as deferred tax assets	-9,609,285	-7,140,251
Income tax expense	-	-

At 31 December 2015 (2014) the Group had loss carryforwards amounting to SEK 131,326 thousand (87 417) that have not been included in calculation of deferred tax.

Parent Company	2015	2014
Profit before tax	-28,763,809	-26,577,337
Income tax calculated at the Group's applicable tax rate, 22%	6,328,038	5,847,014
Income that is exempt from taxation	648	98
Expenses not deductible for tax purposes	-7,291	-57,864
The year's tax loss carryforwards not recognised as deferred tax assets	-6,321,395	-5,789,248
Income tax expense	-	-

At 31 December 2015 (2014) the Parent Company had loss carryforwards amounting to SEK 109,866 thousand (81,109) that have not been included in calculation of deferred tax.

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Note 11 Intangible assets

Group	31 Dec 2015	31 Dec 2014
Patents		
Opening cost	8,994,199	6,647,062
Purchases	2,604,666	2,347,137
Development expenses		
Closing cost	483,702	-
The year's capitalisation	4,643,111	483,702
Closing accumulated cost	16,725,678	9,477,901
Patents		
Opening amortisation	-3,582,892	-1,953,067
The year's amortisation	-1,630,256	-1,629,825
Development expenses		
Opening amortisation	-	-
The year's amortisation	-466,176	-
Closing accumulated amortisation	-5,679,324	-3,582,892
Closing carrying amount	11,046,354	5,895,009

Parent Company	31 Dec 2015	31 Dec 2014
Development expenses		
Opening cost	483,702	-
The year's capitalisation	4,643,111	483,702
Closing accumulated cost	5,126,813	483,702
Development expenses		
Opening amortisation	-	-
The year's amortisation	-466,176	_
Closing accumulated amortisation	-466,176	-
Closing carrying amount	4,660,637	483,702

Note 12 Property, plant and equipment

Group	31 Dec 2015	31 Dec 2014
Opening cost	666,925	628,227
Purchases	128,610	38,698
Closing accumulated cost	795,535	666,925
Opening depreciation	-240,243	-109,025
The year's depreciation	-131,454	-131,218
Closing accumulated depreciation	-371,697	-240,243
Closing carrying amount	423,838	426,682
Parent Company	31 Dec 2015	31 Dec 2014
Parent Company Opening cost	31 Dec 2015 644,500	31 Dec 2014 628,227
Opening cost		628,227
Opening cost Purchases	644,500	628,227
Opening cost Purchases Disposals during the year	644,500 - -3,378	628,227 16,273 -
Opening cost Purchases Disposals during the year Closing accumulated cost	644,500 - -3,378 641,122	628,227 16,273 — 644,500
Opening cost Purchases Disposals during the year Closing accumulated cost Opening depreciation	644,500 - -3,378 641,122 -235,755	628,227 16,273 - 644,500 -109,025

Shares in group companies

Parent Company	31 Dec 2015	31 Dec 2014
Opening cost	150,000	150,000
Investment	228,375	-
Capital infusion	15,750,000	5,950,000
Closing carrying amount	16,128,375	6,100,000

Name	Corporate iden- tification no.	Domicile	% of capital	No. of shares	Equity at 31 Dec 2015
Episurf IP-Management AB	556921-7747	Stockholm	100%	10,000	47,643
Episurf Operation AB	556921-7739	Stockholm	100%	10,000	50,353
Episurf Europe AB	556921-7721	Stockholm	100%	10,000	49,689
Episurf UK Ltd	09548146	Lincoln	100%	1	-3,387,996
Episurf DE GmbH	HRB 218113	Munich	100%		-1,444,289

Note 14. Trade receivables

Group	31 Dec 2015	31 Dec 2014
Trade receivables	199,864	24,344
Less: provisions for doubtful debts	0	0
Trade receivables, net	199,864	24,344

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

On the balance sheet date, collectable trade payables amounted to SEK 200 thousand (24). On the balance sheet date, trade payables amounting to SEK 83 thousand (0) were overdue without any assessed indication of impairment.

Note 15 Inventories

Group	31 Dec 2015	31 Dec 2014
Cost of inventories		
Finished goods	1,154,578	1,473,664
Total inventories before impairment	1,154,578	1,473,664

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

Note	16	Deferred expenses and accrued income
		.,

Group	31 Dec 2015	31 Dec 2014
Prepaid rents	72,100	72,101
Other items	472,964	388,230
Total deferred expenses and accrued income	545,064	460,331
Parent Company	31 Dec 2015	31 Dec 2014
Parent Company Prepaid rents	31 Dec 2015 72,100	31 Dec 2014 72,101
. ,		0110000111

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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 2014	7,956,579	2,386,974
New share issue	8,006,726	2,402,017
Balance at 31 December 2015	15,963,305	4,788,991

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 15,963,305 shares, 3,470,769 were class A shares and 12,492,536 were class B shares.

All shares registered on the balance sheet date were fully paid-up.

Incentive program

At its meeting on 31 March 2015, the Board decided to propose the implementation of a combined bonus and incentive program. Under the program, which is open to all employees in the company, an employee is offered a higher bonus of the received amount is used to subscribe for shares in the company at market price. The AGM on 6 May resolved to implement a combined bonus and incentive program open to all employees in the company.

Other liabilities

Group	31 Dec 2015	31 Dec 2014
VAT liabilities	22,545	-
Personnel-related liabilities	1,053,265	480,735
Other	669,551	198,190
	1,745,361	678,925
Parent Company	31 Dec 2015	31 Dec 2014
		31 Dec 2014
Personnel-related liabilities	455,159	270,269
Personnel-related liabilities Other	455,159 131,415	0.1000011
	,	270,269

Accrued expenses and deferred income

Group	31 Dec 2015	31 Dec 2014
Accrued personnel-related expenses	3,317,243	699,475
Accrued Board fees	500,000	500,000
Accrued consulting fees	915,160	854,169
Deferred income from Vinnova	-	489,104
Other	-	77,249
	4,732,403	2,619,997
Parent Company	31 Dec 2015	31 Dec 2014
Accrued personnel-related expenses	2,014,624	379,145
Accrued Board fees	500,000	500,000
Accrued consulting fees	373,641	854,169
Accrued consulting fees Deferred income from Vinnova	373,641 -	854,169 489,104

Group contributions paid

Parent Company	31 Dec 2015	31 Dec 2014
Episurf IP-Management AB	775,000	375,000
Episurf Operation AB	350,000	356,000
Episurf Europe AB	5,929,000	2,715,000
	7,054,000	3,446,000

Related party transactions

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

Group and Parent Company	31 Dec 2015	31 Dec 2014
Within one year	306,300	308,300
Between one and five years	201,000	216,300
Later than five years	-	_
	507,300	524,600

Obligations under operating leases

The Group leases premises 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.

Consulting fees of SEK 540,000 (810,000) were paid the shareholder and board member Leif Ryd during the period.

Serendipity Professionals AB has received total consulting fees of SEK 1,629,951 (180,000), of which SEK 662,875 referred to re-invoiced expenses, and Serendipity Communications AB has received total consulting fees of SEK 613,265 (210,500). Serendipity Professionals AB and Serendipity Communications AB are companies affiliated with Episurf Medical's largest shareholder, Serendipity Ixora AB.

Board fees to the chairman and other members of the Board were paid in a amount of SEK 100,000 to each, for a total of SEK 500,000 (500,000).

2015	Salary/fees	Variable remuneration	Other benefits	Pension expense	Other remuneration	Total
Board Chairman, Saeid Esmaeilzadeh	100,000					100,000
Board member, Leif Ryd	100,000				540,000	640,000
Board member, Jeppe Magnusson	100,000					100,000
Board member, Thomas Nortoft	100,000					100,000
Board member, Robert Charpentier	100,000					100,000
CEO until May 2015, Nina Bake	404,480			75,700		480,180
CEO as of July 2015, Rosemary Cunningham Thomas	727,968	283,842		60,000		1,071,810
Other senior executives	3,329,228	449,339		248,826		4,027,393
Total	4,961,676	733,181	-	384,526	540,000	6,619,383

2014	Salary/fees	Variable remuneration	Other benefits	Pension expense	Other remuneration	Total
Board Chairman, Saeid Esmaeilzadeh	100,000					100,000
Board member, Leif Ryd	100,000				810,000	910,000
Board member, Jeppe Magnusson	100,000					100,000
Board member, Thomas Nortoft	100,000					100,000
Board member, Robert Charpentier	100,000					100,000
CEO Nina Bake	910,320	1,200,000		165,681		2,276,001
Other senior executives	2,371,749			110,534		2,482,283
Total	3,782,069	1,200,000	-	276,215	810,000	6,068,284

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Variable remuneration for the financial years 2015 and 2014 is an expensed bonus, to be paid in 2016 and 2014.

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

The Board Chairman has not received any remuneration other than Board fees.

Bonus

A bonus for 2015 has been paid to all of the company's employees, since the established targets were met.

Termination benefits

Between the CEO Rosemary Cunningham Thomas 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 2

Events after the balance sheet date

- » Episurf Medical received CE mark approval for its fifth product, Epioscopy™ Damage Assessment Tool.
- » Episurf Medical launched a German website and intensified its marketing activities in the region.
- » Episurf Medical announced that the company now has 100 users approved and connected to the µiFidelity® platform.
- » The scientific abstract "On the attachment of cartilage to HA: Signs of "chondrointegration" Studies on the Episealer® mini-prosthesis in the sheep knee" was granted a poster presentation at orthopaedic conference ESSKA.
- » A fourth sales representative was hired in Germany.
- » A second sales representative was hired for the Nordic region.
- » Episealer® was approved by Spire Hospital in the UK for private insurance patients.

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Statement of assurance

The Board of Directors and Chief Executive Officer hereby give their assurance that the consolidated accounts and annual accounts have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU and give a true and fair view of the financial position and results of operations of the Parent Company and the Group.

The administration report for the Group and the Parent Company gives a true and fair

view of the business activities, financial position and results of operations of the Group and the Parent Company and describes the significant risks and uncertainties to which the Group companies are exposed.

The income statements and balance sheets of the Parent Company and the Group will be put before the AGM on 24 May 2016 for approval.

Stockholm, 20 April 2016

Saeid Esmaeilzadeh
Board Chairman
Board member

Thomas Nortoft

Board member

Leif Ryd Board member

Rosemary Cunningham Thomas

CEO

Robert Charpentier

Board member

Out auditor's report was submitted on 20 April 2016 $$\operatorname{KPMG}\nolimits$ AB

Duane Swanson

Authorised Public Accountant

EPISURF MEDICAL ANNUAL REPORT 2015

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Auditor's report

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

Report on the annual accounts and consolidated accounts

We have audited the annual accounts and consolidated accounts of Episurf Medical AB (publ) for the year 2015, except for the corporate governance statement on pages 39-43. The annual accounts and consolidated accounts of the company are included in the printed version of this document on pages 32-73.

Responsibilities of the Board of Directors and the Managing Director for the annual accounts and consolidated accounts

The Board of Directors and the Managing Director are responsible for the preparation and fair presentation of these annual accounts in accordance with the Annual Accounts Act and of the consolidated accounts in accordance with International Financial Reporting Standards, as adopted by the EU, and the Annual Accounts Act, and for such internal control as the Board of Directors and the Managing Director 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.

Auditor's responsibility

Our responsibility is to express an opinion on these annual accounts and consolidated accounts based on our audit. We

conducted our audit in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the annual accounts and consolidated accounts are free from mate-rial misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the annual accounts and consolidated accounts. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the company's preparation and fair presentation of the annual accounts and consolidated accounts 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. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the Board of Directors and the Managing Director, as well as evaluating the overall presentation of the annual accounts and consolidated accounts.

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

Opinions

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act, and present fairly, in all mate-rial respects, the financial position of the parent company as of 31 December 2015 and of their financial performance and cash flows 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 2015 and of their financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards, as adopted by the EU, and in accordance with the Annual Accounts Act. Our opinions do not cover the corporate governance statement on pages 39-43. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

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

Other matters

The audit of the annual accounts for year 2014 was performed by another auditor who submitted an auditor's report dated 31 March 2015, with unmodified opinions in the Report on the annual accounts and consolidated accounts.

Report on other legal and regulatory requirements

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the proposed appropriations of the company's profit or loss and the administration of the Board of Directors and the Managing Director of Episurf Medical AB (publ) for the year 2015. We have also conducted a statutory examination of the corporate governance statement.

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, and the Board of Directors and the Managing Director are responsible for administration under the Companies Act, and that the corporate governance statement on pages 39–43 has been prepared in accordance with the Annual Accounts Act.

Auditor's responsibility

Our responsibility is to express an opinion with reasonable assurance on the proposed appropriations of the company's profit or loss and on the administration based on our audit. We conducted the audit in accordance with generally accepted auditing standards in Sweden.

As basis for our opinion on the Board of Directors proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

As basis for our opinion concerning discharge from liability, in addition to our audit of the annual accounts and consolidated accounts, we examined significant decisions, actions taken and circumstances of the company in order to determine whether any member of the Board of Directors or the Managing Director is liable to the company. We also examined whether any member of the Board of Directors or the Managing Director has, in any other way, acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

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

Furthermore, we have read the corporate governance statement and based on that reading and our knowledge

of the company and the group we believe that we have sufficient basis for our opinions. This means that our statutory examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted audit standards in Sweden.

Opinions

We recommend to the annual 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.

A corporate governance statement has been prepared, and its statutory content is consistent with the other parts of the annual accounts and consolidated accounts.

Stockholm, 20 April 2016

KPMG AB

Duane Swanson

Authorised Public Accountant

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Annual General Meeting

Episurf Medical AB (publ) will hold its Annual General Meeting on Tuesday, 24 May 2016, at 6:00 p.m. at 7A Odenplan, Odengatan 65, 113 22 Stockholm, Sweden.

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 Saeid Esmaeilzadeh (Chairman of Episurf Medical AB) Ashkan Pouya (representing Serendipity Ixora AB) Peter Ragnarsson (representing LMK Stiftelsen)

Björg Arnardóttir (representing Kaupthing HF.) The Chairman of the AGM is Ashkan Pouva.

Participation and registration

Shareholders who wish to participate in the AGM must be recorded in the share register maintained by Euroclear Sweden AB by Wednesday, 18 May 2016, and must register to participate by Wednesday, 18 May 2016.

Registration can be sent by mail to: Episurf Medical AB, Stora Skuggans Väg 11, 115 42, 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, 17 May 2016. The shareholder must notify the trustee of this in good time prior to this date.

Financial calendar

Interim report January-March 2016: 24 May 2016 Interim report January–June 2016: 19 August 2016 Interim report January-August 2016: 4 November 2016 Year-end report for 2016: 24 February 2017

Financial reports and issued press releases are available from the date of publication on Episurf Medical's website www.episurf.com. The annual report is available as a PDF document on the company's website and the printed annual report will be sent to those who so request. Orders can be sent to ir@episurf.com, or by mail to Episurf Medical AB, Stora Skuggans Väg 11, SE-115 42, Stockholm, Sweden.

IR contact



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Rosemary Cunningham Thomas,

CEO

Phone: +46 70 765 58 92,

e-mail: rosemary.cunninghamthomas@episurf.com

Glossary

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 correct any problems (a type of keyhole surgery).

Cartilage: The smooth, rubbery layer of shiny, white connective tissue that covers the end of bones at the joints. This tissue allows movement with low friction.

Cartilage defect of grade III: Deep fissuring in the cartilage without exposed bone.

Cartilage defect of grade IV: Deep fissuring in the cartilage with exposed bone.

CE marking: CE marking is a manufacturer's or importer's declaration that a product meets the EU's fundamental health, environmental and safety requirements. The product in question undergoes a conformity assessment by a Notified Body, which decides whether the product fulfils the applicable product requirements in the EU. 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.

Cobalt: A metallic material that is used knee prostheses.

CT scan: Computer tomography. Used in medical diagnostics to generate a three-dimensional image of the patient.

Debridement: See Microfracture.

Degenerative origin: Degenerative origin refers to conditions in which the cells, tissues or organs deteriorate and lose function. In degenerative joint disease, the deterioration is due to wear and tear or breakdown of cartilage.

FDA: US Food and Drug Administration.

Focal cartilage defect: A cartilage defect in a well defined area

Hyaline cartilage: Natural cartilage.

Hydroxyapatite: is a naturally occurring mineral that is a major component of human bone tissue and the main mineral of which dental enamel and dentin are composed.

Incidence: The rate of newly diagnosed cases of a disease within a specified period of time.

Invasive treatment alternative: Treatments that require a surgical procedure.

Knee osteotomy: See Wedge osteotomy.

KOL: Key Opinion Leaders, prominent and opinion-leading surgeons.

Microfracture: A 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 surgical technique for treatment of cartilage defects in which a special instrument is used to harvest cylindrical cartilage plugs from less weight-bearing surfaces of the knee joint and insert them into the defective section of cartilage.

MRI: Magnetic resonance imaging. MRI is an imaging technology for medical diagnostics that uses an MRI scanner to create detailed images of the body.

Orthopaedics: The branch of medicine concerned with the correction of deformities and functional impairments in the musculoskeletal system, which includes treatment of spine injuries and peripheral nerve damage.

Osteoarthritis: Osteoarthritis is type of joint disease that is characterised by loss of joint function with varying destruction of joint cartilage and the underlying bone.

Osteochondral autograft procedure: See Mosaicplasty.

Osteochondral defect: Underlying bone defect.

Osteotomy: A surgical procedure in which a bone is cut and reshaped to change its alignment and thereby relieve pressure on the joint.

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.

Traumatic damage: Damage caused by an outside force, such as fall injuries.

Wedge osteotomy: A surgical technique in which a wedge is cut from either the tibia or the femur to alter the biomechanical load on the knee joint.

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