

# Episurf Medical presents strategy update, new external financing and long-term operating targets

Episurf Medical (NASDAQ: EPIS B) today presents a strategy update, a new financing agreement and long-term operating targets. The company is close to launching an important and comprehensive clinical multicenter study in the US and Europe and the company has entered into early collaborative discussions regarding the US market.

Episurf Medical addresses significant medical needs not currently met by the orthopaedic industry, and the company's vision is to bring more people back to fully living life. The business implementation of this vision is to provide orthopaedic surgeons with clinically superior patient-specific treatments using Episurf's proprietary image analysis, implant design and manufacture technologies. The Episealer® technology, now rapidly gaining traction in Europe on the strength of very promising study results, represents a unique treatment method for an orthopaedic treatment gap of significant size globally. Against this background, the Board of Episurf Medical has resolved on long-term operational targets and several international growth initiatives, and has also taken the decision to pursue a clinical study aimed at gaining FDA-approval for the Episealer® knee technology.

**Long-term operational goal:** Episurf Medical will establish its patient-specific technology in the treatment algorithm for focal cartilage and bone lesions to become a highly profitable and innovative company in the orthopaedic industry.

**Long-term market share goal:** Episurf Medical estimates that its addressable market for Episealer® knee implants in Europe, Asia and the US amounts to 150,000 patients annually, and its goal is to achieve a 10% penetration of this market, for annual sales of 15,000 units.

**Long-term profitability goal:** Episurf Medical targets a long-term operating margin of 40% driven by improvements in gross margins driven by significant increases in the automation of the company's process for damage assessment and by large scale economies expected as manufacturing steps are brought in-house and the supply chain is optimised.

In an important step towards executing this strategy, the company has signed an agreement relating to a financing of up to SEK 70 million. The transaction will be carried out through the issuance of convertible notes with warrants attached in several tranches spread over 36 months. The financing is conditioned upon the shareholders approving the financing and the board of directors will propose to the annual shareholders' meeting, on 9 April 2018, to take such a decision. The company has today issued a separate press release regarding the new financing.

Pål Ryfors, CEO Episurf Medical: *"Our technology works, and patients are doing significantly better. That is the basis for the success of the Episealer technology. The treatment gap is well identified and while we are still only scratching the surface of our business opportunities, current business volumes suggest that Episurf has entered the next development phase. I am happy that we have secured financing for a very important multicenter study in the US and in Europe. Thereby, we can really start our US launch. This financing provides great flexibility and works very well for us. Our continued internationalisation is just a logical next step and we will soon be able to provide the market with a second product based on the Episealer technology, namely the Episealer Talus implant. Our long-term targets are ambitious, but the clinical performance has put us in a strong position and we have a great opportunity to successfully execute on our strategy to reach our targets."*

**Episurf Medical's newly refined strategy rests on four key pillars:**

- **Produce clinical and health economic data supporting the Episealer® technology**
- **Establish the Episealer® technology with a large user base of orthopaedic surgeons and Key Opinion Leaders globally**
- **Secure production and reimbursement enabling high margins**
- **Continue our record of innovation to ensure technological relevance**

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

Late 2017, the first peer-reviewed results from a multicenter study were published showing good-to-excellent results. Additional case reports and patient follow-ups from patients who have exceeded 3 – 5 years since surgery strengthen our view that the Episealer® technology will deliver excellent long-term results. The Episealer is evaluated in a number of clinical studies and the company is about to launch a large multicenter study in the US and in Europe. Episurf Medical is currently planning to set up an IDE (Investigational Device Exemption) clinical trial in US and European centers for the Episealer® knee implants. The study to be conducted under the IDE will form an important part of Episurf Medical's PMA (premarket approval) application to the FDA for US market approval.

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

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

- Episurf is considering additional European markets constituting a mix between distribution and direct markets.
- The company has engaged in distributor discussions in a number of Middle Eastern markets.
- The company is in early distributor discussions for a number of Asian markets, following a regulatory review.
- In the US market, the company aims at starting clinical study for the purpose of receiving FDA approval for marketing of the Episealer® technology. The study will run as a combined US and European multicenter study.
- As previously communicated, execution of our strategy might best be pursued together with a partner, and Episurf Medical is currently in early collaborative discussions.

Dennis Stripe, Chairman Episurf Medical: *"The world of Orthopedics, specifically the implant market, has a history of continued innovation. We have talked about this before, and in 2017 the worldwide market saw continued innovation and improved patient care. Our goal of being a global company is focused on markets we can successfully enter, and the team is executing a very direct and well thought out plan. We realize that every decision we make can affect shareholder value, and we minimize our risks through a well-developed tactical plan. While the overall global orthopaedic market has settled down after consolidations of the past few years, we see acceptance of new technologies. We see the acceptance of robotic surgery, increasing material research and of course patient specific diagnosis and resolutions for orthopedic problems, this is Episurf! The growth in the number of surgeons using the Episealer® and their feedback indicates that we have successfully found a gap, an unmet need in the market. There have been several attempts by industry to answer this treatment gap, however we cannot see any better alternative than Episurf."*

**Secure production and reimbursement enabling high margins**

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

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

- Episurf Medical has decided to introduce a new joint implant to the market, and the company has developed a personalized implant for the ankle. Episurf Medical is targeting a significant treatment gap for osteochondral ankle defects and the implant is based on the same technology platform as the company's knee implants.
- The company continues to develop its imaging technology and following the launch of the ankle implant, this product has the highest priority in the company's product development pipeline.

**For more information, please contact:**

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**About Episurf Medical**

*Episurf Medical is endeavoring to bring people with painful joint injuries a more active, healthier life through the availability of minimally invasive and personalized treatment alternatives. Episurf Medical's Episealer® personalized implants and Epiguide® surgical drill guides are developed for treating localized cartilage injury in joints. Episurf Medical's µiFidelity® system enables implants to be cost-efficiently tailored to each individual's unique injury for the optimal fit and minimal intervention. Episurf Medical's head office is in Stockholm, Sweden. Its share (EPIS B) is listed on Nasdaq Stockholm. For more information, go to the company's website: [www.episurf.com](http://www.episurf.com).*

*This information is information that Episurf Medical AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 08.25 CET on 23 February 2018.*