



**Implantica**

Interim Report Jan-Mar 2022

## Financial summary

*Figures within parentheses refer to the preceding year.*

### First quarter

- Net sales increased 141% to TEUR 198 (82).
- Adjusted gross margin amounted to 95% (91%).
- Operating loss (EBIT) increased to TEUR 4,411 (2,279).
- Loss after tax amounted to TEUR 4,888 (1,966).
- Basic and diluted loss per Class A share amounted to EUR 0.07. (0.03).
- Cash and short-term investments as at the end of the period amounted to MEUR 125.7.

## Significant events

### In the first quarter of 2022

- Implantica continued during this quarter to substantially strengthen its organisation on a broad front. Since our vision is to become the world leader in smart medical implants, we embrace the fact that the talent and calibre of our people are fundamental to achieve this goal. This shared vision has attracted world-class talent from diverse leading organizations.
- First RefluxStop™ implants successfully performed in the UK at King Edward VII Hospital in London by Mr. Nick Boyle, Founder of RefluxUK and VP of the European Foregut Society.
- Comprehensive eHealth patent applications filed for Implantica's platform technology encompassing 25'000 pages, providing fundamental coverage for the eHealth platform in general and extending the scope and term of patent protection for the pipeline products.
- Implantica successfully progresses with eHealth adaption of our pipeline products culminating in a 3-day eHealth workshop with 20 experts from all over Europe to advance the usability of our unique eHealth platform technology, designed to change treatment on distance.

### After the end of the period

- Successfully completed RefluxStop™ EU MDR (Medical Device Regulation) Technical Documentation submission.
- Long anticipated return to physical attendance at health-care Congresses since the Covid outbreak, receiving an enthusiastic reception from KOLs for RefluxStop™ at the German Surgeons' Congress in Leipzig, Germany and Gastrodagarna in Malmö, Sweden, among others.
- Further developing our market access strategy focussing on large centers of excellence and important KOLs in important markets. In Japan, we have been approved by the government-controlled company Jetro, which supports selected companies with important technologies with market entry in Japan.
- Our regulatory and clinical teams have been diligently preparing the extensive RefluxStop™ PMA application, for FDA approval in US. We also continued to expand our presence in our US subsidiary, Implantica Inc.



# Successful RefluxStop™ market access strategy

“With our first disruptive product RefluxStop™, Implantica has a multi-billion-dollar business opportunity within our reach, well supported by our 4-year results and feedback from our KOLs.”

## Commercialisation of RefluxStop™

As previously mentioned, our US approval process has made great progress since the FDA (Food and Drug Administration) has agreed to receive a PMA (Premarket Approval) marketing application for RefluxStop™ based solely on our existing European clinical data. Our regulatory and clinical teams have been diligently preparing the extensive PMA application, including compiling the additional clinical data requested by FDA and preparing a US-based usability study on cadavers. We also continued to expand our presence in our US subsidiary, Implantica Inc.

We continue with maximum efforts to focus on the commercialisation of RefluxStop™, which has all attributes to become the new standard of care in treatment of acid reflux. This is fuelled by excellent clinical trial results, today up to 4 years, which reinforce RefluxStop's™ superior outcome.

RefluxStop™ presents fewer complications than the competition since it does not compress the food passageway. Side effects with current procedures such as swallowing difficulties, pain at swallowing, inability to belch and vomit as well as gas bloating have been dramatically reduced.

RefluxStop™ is also designed to treat acid reflux better since it treats the cause of acid reflux. It is very important to restore a low pH in the lower esophagus, as RefluxStop™ does, because acid reflux causes cancer. In the EU and US alone 48'000 deaths are expected from esophageal adenocarcinoma mainly caused by acid reflux.

The reason for this large number of deaths is that drug therapy with PPIs does not protect from this cancer risk, and no proof of such risk reduction can be found in the literature. Note that esophageal adenocarcinoma in men in the western world has increased tenfold over the past 40 years despite the introduction of PPIs in 1988.

We have increased our efforts to maximize commercial success through a dedicated market access strategy. Implantica set the foundation for RefluxStop™ global growth through focused market development activities going global with RefluxStop™ within our geographic focus. This will be



CEO Peter Forsell

supported by continuing to gather solid cost-benefit evidence of our novel device over existing therapies. Our new Payer Advocacy and Health Economics team are focusing on reimbursement achievement with insurance companies and governmental agencies in the US and globally.

Our market strategy also involves supplying robust RefluxStop™ clinical evidence through a registry study and randomized clinical investigation.

It's important to not lose sight of the magnitude of this treatment field: One billion people worldwide take at least one cure of PPI annually and 17% of the EU population have weekly acid reflux!

Altogether this supports that Implantica has a multi-billion-dollar business opportunity within our reach, with our first disruptive commercially available RefluxStop™ solution. With the right strategy and execution, RefluxStop™ has great potential to become the new standard of care for GERD surgical treatment and build substantial value for our Investors.

## The market

During the quarter, we have been utilizing and further developing our market access strategy, focusing on large centers of excellence and important KOLs in important markets, in particular the US, UK, Germany and Japan. In Japan, we have been approved to receive support for our market entry by the government-controlled company Jetro, which supports selected and important companies' market entry in Japan. We have received market feedback further increasing our conviction that RefluxStop™ has tremendous potential to become a success story.

Overall, the global implantable medical device market is expected to reach USD 168.3 billion by 2027, representing a compound annual growth rate of 5.5% over the next 5 years.



Our eHealth pipeline works within a market space forecasted to reach USD 230 billion by 2027.

We have started to focus on regulatory approval in Japan, another important market. During the quarter we started performing surgeries in the UK and will focus to build up the UK market. In parallel, we have employed a competent sales/market access team in Italy and Spain. However, our main focus is the US.

## A shared vision

Implantica has continued during this quarter to substantially strengthen its organisation on a broad front. Since our vision is to become the world leader in smart medical implants, we embrace the fact that the talent and calibre of our people are fundamental to achieve this goal. People come to Implantica because they believe they can be a part of an exciting journey that revolutionizes patient care for debilitating conditions across a range of disease states by using cutting edge technology. This shared vision has attracted world-class talent from diverse leading organizations such as NASA, Massimo, Ericsson, Medtronic, AstraZeneca as well as from leading universities around the world. Implantica's employees have shown to be talented and passionate about their jobs and very dedicated to our mission: making the next generation of surgical products and eHealth a standard of care that will empower patients to be more in control of their condition and quality of life.

Today we have a remarkable team of mechanical and software engineers, growing sales, market development and access teams and more growth across all functional areas. We're building apps, we're creating connected implants, we're working with payers, we're in the OR with the top surgeons in our field. We should not forget our patent team where we recently filed an eHealth patent application comprising 25'000 pages to secure future value growth.

We are happy we have been able to reinforce our team with such excellent competencies, and it's exciting to be the CEO of a company with so many talented people that can share our vision and values.

## eHealth pipeline

We have successfully continued to develop our eHealth platform to be able to treat diseases in a way which were previously seen as untreatable. eHealth will save costs – reduce hospital stay and number of visits to the hospital. eHealth will bring treatment closer to the patient – patient will be involved and more in charge.

While most development regarding eHealth is focused on gathering information from outside the patient's body, Implantica's eHealth-system is designed to monitor, deliver

and handle data as well as treat illnesses from inside the body. This enables a reduced cost of care and better patient outcomes. The future of eHealth will be the Medtech 3.0 revolution.

Entering Medtech 3.0 with Implantica's eHealth platform, designed for a future where the patient and physician have direct interaction with their tech-enabled care or enhancement continuously - wherever they are.

Implantica has a head start in this intersection of technology from traditional MedTech and rapidly evolving digitalization. The management sees enormous potential in Implantica's mission and intriguing portfolio of upcoming products that are in the forefront of this eHealth revolution. Our team is looking forward to the exciting challenges ahead of us.

As mentioned, Implantica's eHealth-system facilitates that the patient can be more involved in his or her condition and treatment. eHealth helps the patient be informed and engaged. It eases the burden and makes the treatment part of everyday life. It is designed to let the physician and the patient conveniently meet on distance to follow-up on the condition and treatment without having to meet in person, saving time and resources.

The eHealth platform technology adaption to our pipeline products has taken a large step forward during the quarter. Implantica's eHealth platform is designed to be able to change treatment on distance, saving substantial costs for society.

## Going forward

We are in an exciting phase with our new technology, and we foresee Implantica mid-term to be in the forefront of the smart implant and eHealth revolution.

Looking ahead, we have a strong balance sheet to support our key business goals, most importantly, build and scale our top commercial priority RefluxStop™ while finalising development of the targets in our eHealth R&D pipeline.

Implantica has all the attributes to become an exceptional growth story with an exciting journey in front of us and that's why we manage to attract such exceptional talents to Implantica.

I would like to take this opportunity to thank our employees, partners and shareholders for their continued commitment, tireless efforts, and dedication in executing Implantica's bold strategy to enrich patients' lives with our ground-breaking technologies.

### **Peter Forsell**

CEO and Founder, Implantica  
*Surgeon and Inventor*