

# Implantica publishes Year-end Report, January – December 2024 (Q4)

#### **REFLUXSTOP™ FDA MILESTONE**

# Significant events in the fourth quarter

- Submitted extensive clinical Module 2 of the 3 module-process in the Premarket Approval (PMA) application to U.S. FDA. Most crucial module containing clinical portion including 5-year long-term follow-up of CE mark pivotal study
- Reached a milestone of the first 1,000 RefluxStop™ procedures performed. Over 40 leading anti-reflux hospitals across Europe actively perform the RefluxStop™ procedure today
- Expansion in the UK NHS public hospital network continued with Chelsea &
  Westminster Hospital in London joining the RefluxStop™ centers
- Highly successful 3rd Global Annual RefluxStop™ meeting conducted in London, attended by 110+ anti-reflux surgeons and GI doctors – almost three times the amount that attended last year – from all over Europe, US and Canada
- Health economic study from Sweden performed in partnership with Prof. Lars Lundell from Karolinska Institute was published and shows RefluxStop™ is a highly cost effective long-term alternative for the Sweden Healthcare System

### Significant events after the end of the period

- Module 1 was accepted and closed by U.S. FDA in our RefluxStop™ Premarket Approval (PMA) application
- FDA completed its review of the PMA Clinical Module 2 and provided its written feedback, which the company considers to be very positive and will continue to work with FDA to bring RefluxStop to the U.S. market as soon as possible
- Results from the largest real-world RefluxStop™ study published, involving 79 patients for up to 17 months follow-up in Germany showing median improvement in quality of life questionnaire, GERD-HRQL of 100%
- World-leading and largest hospital in Spain, La Paz University Hospital in Madrid, performed their first RefluxStop™ surgeries, representing the 12th center of excellence in Spain to be onboarded
- Abstract showing the cost-effectiveness analysis for RefluxStop™ in Italy won the prestigious Top 5% Award at the leading payer health-economics congress, ISPOR

# Fourth quarter financial summary

- Net sales decreased 13% to TEUR 442 (508) (due to trial devices, see full year).
- Adjusted gross margin amounted to 90% (92%).
- Impairment expense relating to capitalized R&D and patents of TEUR 1,669 (0) impacting EBIT.
- Operating loss (EBIT) increased to TEUR 7,174 (6,942).
- Loss after tax amounted to TEUR 7,339 (8,734).
- Basic and diluted loss per Class A share amounted to EUR 0.10 (0.12).
- Cash as at the end of the period amounted to MEUR 64.6.



# Full year financial summary

- Net sales increased 38% to TEUR 1,936 (1,408).
- Adjusted gross margin amounted to 92% (94%).
- Operating loss (EBIT) increased to TEUR 25,466 (21,840).
- Loss after tax amounted to TEUR 23,686 (24,502).
- Basic and diluted loss per Class A share amounted to EUR 0.34 (0.34).

### Telephone conference

Implantica will hold a teleconference on 14 February 2025 at 15:00 (CET) with Peter Forsell (CEO), Andreas Öhrnberg (CFO), and Nicole Pehrsson (Chief Corporate Affairs Officer). Please see the dial-in details below to join the conference:

#### Webcast:

https://implantica.events.inderes.com/q4-report-2024

#### Dial-in:

numbers to the teleconference will be received by registering on the link below. After the registration, you will be provided phone numbers and a conference ID to access the conference

https://conference.inderes.com/teleconference/?id=5001390

# For further information, please contact:

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Implantica is listed on Nasdaq First North Premier Growth Market in Stockholm. The company's Certified Adviser is FNCA Sweden AB, info@fnca.se

This information is information that Implantica AG is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-02-14 08:00 CET.

# **About Implantica**

Implantica is a medtech group dedicated to bringing advanced technology into the body. Implantica's lead product, RefluxStop™, is a CE-marked implant for the prevention of gastroesophageal reflux that will potentially create a paradigm shift in anti-reflux treatment as supported by successful clinical trial results. Implantica also focuses on eHealth inside the body and has developed a broad, patent protected, product pipeline based partly on two platform technologies: an eHealth platform designed to monitor a broad range of health parameters, control treatment from inside the body and communicate to the caregiver on distance and a wireless energising platform designed to power remote controlled implants wirelessly through intact skin. Implantica is listed on Nasdaq First North Premier Growth Market (ticker: IMP A SDB). Visit www.implantica.com for further information.