

# Implantica publishes Interim Report January – September 2025 (Q3)

# REFLUXSTOP® NEARS FDA APPROVAL – STRONG MOMENTUM TOWARD US MARKET ENTRY

## Significant events in the third quarter of 2025

- Received positive feedback from the FDA on the final PMA Module 3 submission
- Expanded production by 10,000 RefluxStop® units, ensuring readiness for rapid U.S. scale-up following FDA approval
- Built two new production tools, including one located in the U.S. to support local manufacturing
- RefluxStop® generated exceptional enthusiasm at the 2025 American Foregut Society (AFS)
   Annual Meeting
  - Hosted a standing-room only clinical panel of leading RefluxStop® experts highlighting outstanding pivotal study 5-year outcomes to over 100+ attendees
  - Presented the largest real-world safety data to date 602 patients from 22 centers across
     Europe receiving strong engagement from U.S. surgeons

## Significant events after the end of the period

- Completed the 100-Day FDA meeting, providing clarity on final approval steps, confirming that the remaining PMA requirements for RefluxStop® are clear and addressable
- FDA Bioresearch Monitoring (BIMO) inspections of Implantica and a study Site as well as
  inspections of Implantica's Quality System and the production facility for RefluxStop® concluded
  without major findings, as reported in the closing meetings

# Financial summary third quarter 2025

- Net sales increased 6% to TEUR 365 (344).
- Adjusted gross margin amounted to 93% (97%).
- Operating loss (EBIT) decreased to TEUR 4,432 (5,336).
- Loss after tax decreased to TEUR 4,415 (6,444).
- Basic and diluted loss per Class A share amounted to EUR 0.06 (0.09).
- Cash and short-term investment as at the end of the period of MEUR 53.3

### First nine months

- Net sales increased 3% to TEUR 1,543 (1,494).
- Adjusted gross margin amounted to 94% (93%).
- Operating loss (EBIT) decreased to TEUR 13,130 (18,292).
- Loss after tax decreased to TEUR 12,627 (16,347).
- Basic and diluted loss per Class A share amounted to EUR 0.18 (0.23).

#### Telephone conference

Implantica will hold a teleconference on 31 October 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

If you wish to participate via webcast, please use the following link:

https://implantica.events.inderes.com/q3-report-2025



#### Dial-in

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=5009354

## 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 2025-10-31 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.