



bioretec

better healing – better life

bioretec

Q1 2025 Investor Presentation / 21.5.2025

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Presenting today



**Sarah van Hellenberg
Hubar-Fisher**
Interim CEO

At Bioretec since 2021

Previous experience:



Johanna Salko
CFO

At Bioretec since 2021

Previous experience:



The first osteopromotive, load-bearing absorbable orthopedic implant

- ✓ **Breakthrough technology:**

First absorbable osteopromotive magnesium implant approved in the US

- ✓ **Clinically proven:**

Bone healing in 12 weeks, fully absorbed by the body in 2-3 years

- ✓ **Regulatory authorisations:**

CE-marked trauma screw portfolio, LAG screw for foot and ankle
FDA-approved

- ✓ **Strong pipeline:**

DrillPins, Staples, Plates, IM-nails, and Spinal Cages on the way

- ✓ **Clear commercial plan:**

Strategy in place for full RemeOs product family rollout



RemeOs™

Aiming to transform the orthopedic implant market

Anticipated benefits for surgeons:

- ✓ Fixation strength on par with traditional metals
- ✓ No workflow disruption, same technique as traditional implants
- ✓ Patient demand and satisfaction: reduced allergic reactions and complications
- ✓ Higher value-add primary operations

Primary operation



Secondary removal operation



Anticipated benefits for patients:

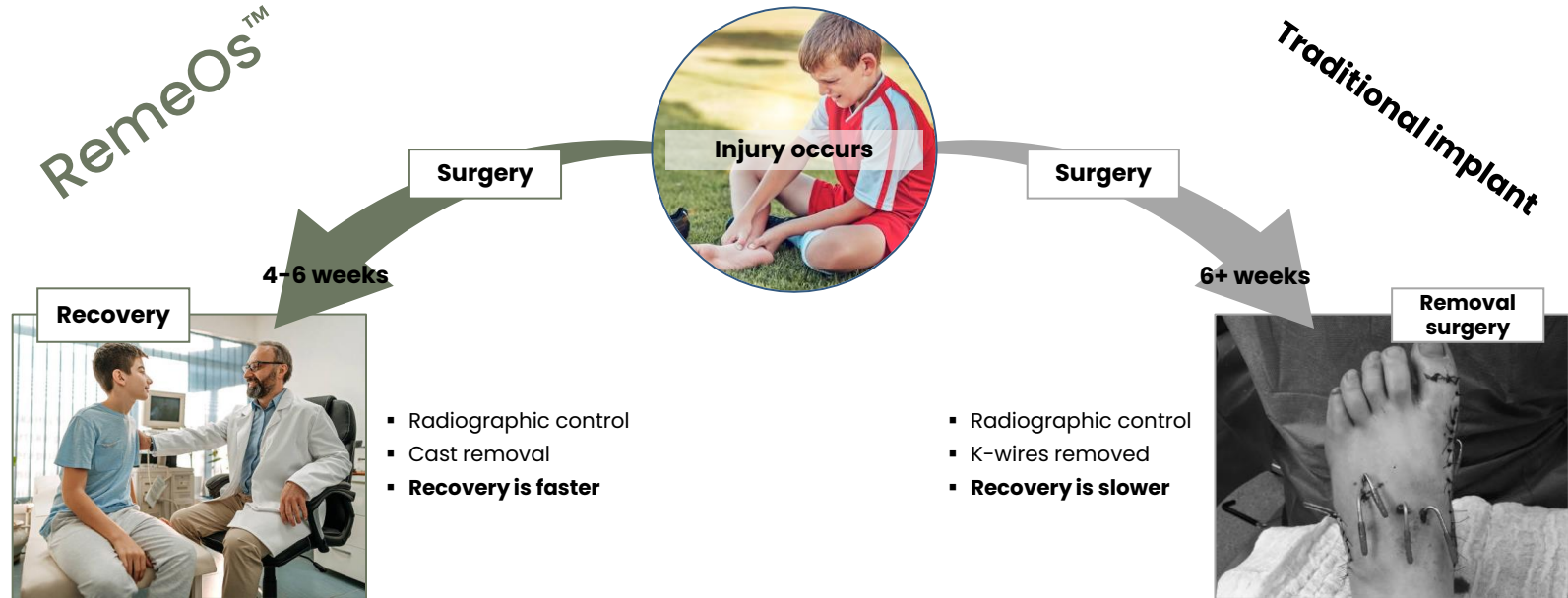
- ✓ Eliminates the need for secondary surgeries
- ✓ Reduced risk of patient complications
- ✓ Faster healing, shorter recovery time

Anticipated benefits for healthcare system:

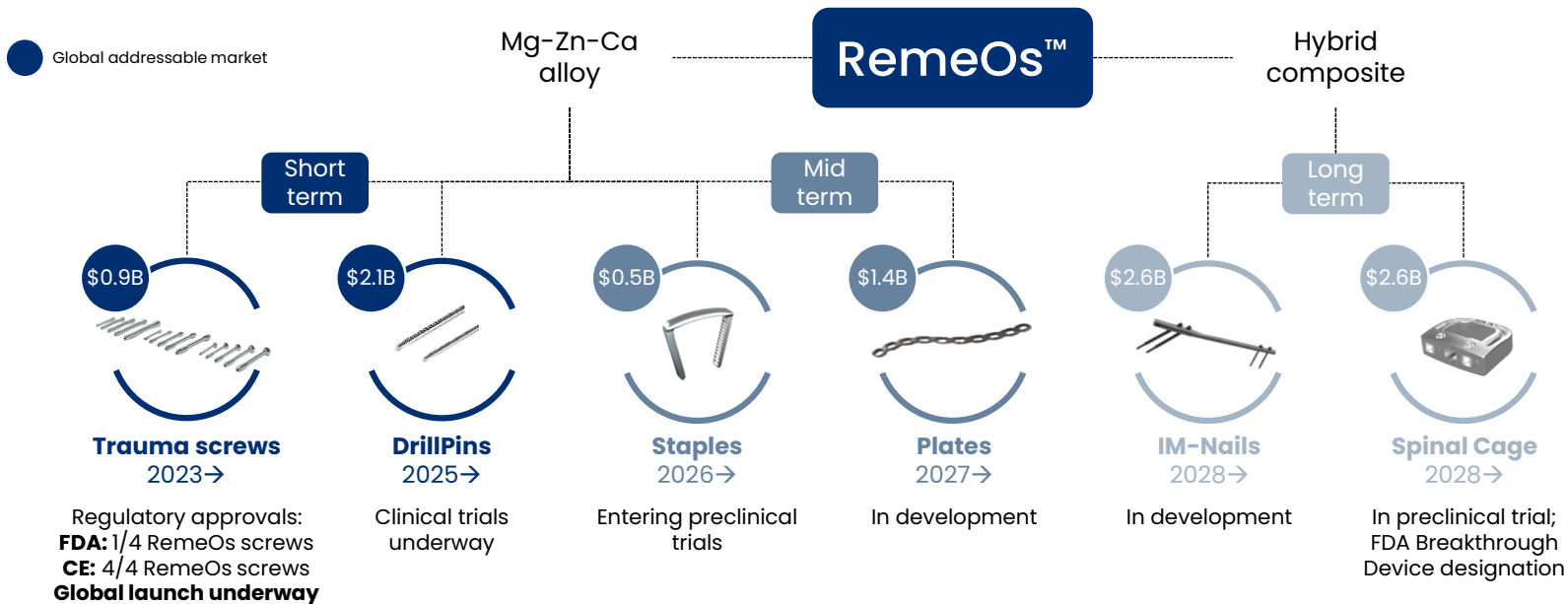
- ✓ Reduced surgical waste
- ✓ Lower total cost of care

! E.g. in Germany, an ankle hardware removal can cost EUR 8,200

Hypothetical example: RemeOs improving the patient experience



Significant product launches planned in the next 3 years



By expanding the product portfolio, Bioretec aims to enhance sales efficiency and strengthen Bioretec's position as a recognized supplier of best-in-class orthopedic implants

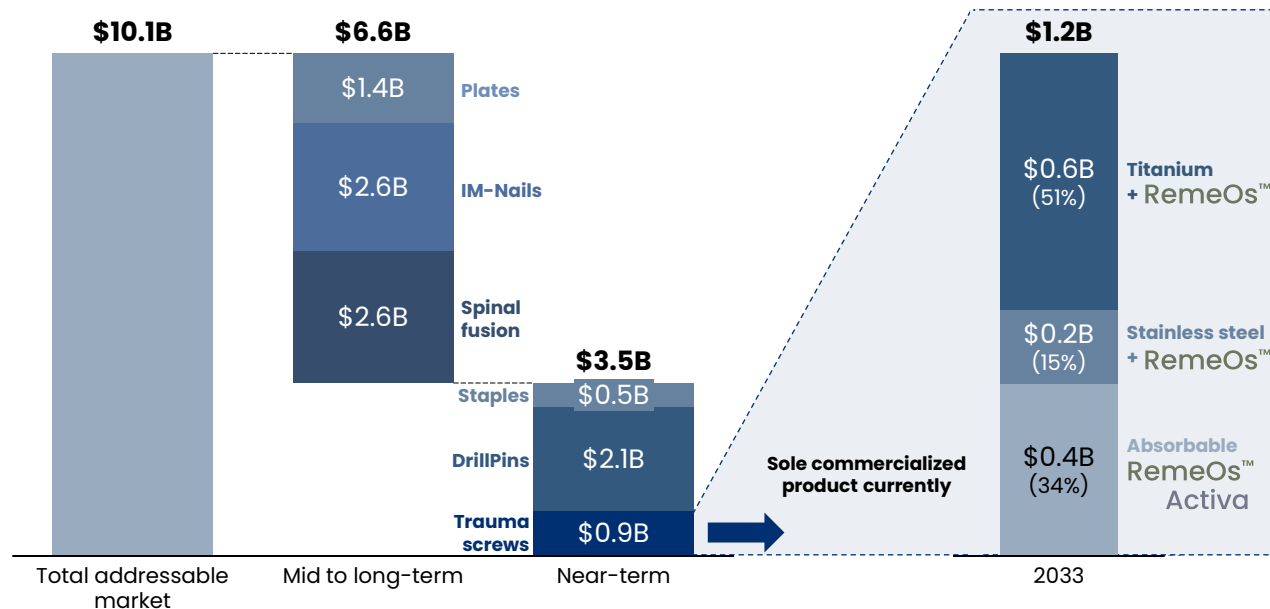
Source: Global Data report 2023, Orthoworld report 2024

\$10B+ market potential with strong absorbables outlook

Addressable market for full product line-up >\$10B...

... with strong absorbables outlook

Addressable market, 2024 estimate



Trauma Screw market alone to reach ~\$1.2B by 2033

Titanium and steel are currently used in high load-bearing situations

RemeOs has potential to capture share from full addressable market due to its matching fixation strength

Source: Global Data report 2023, Orthoworld report 2024

Commercialisation in the US underway

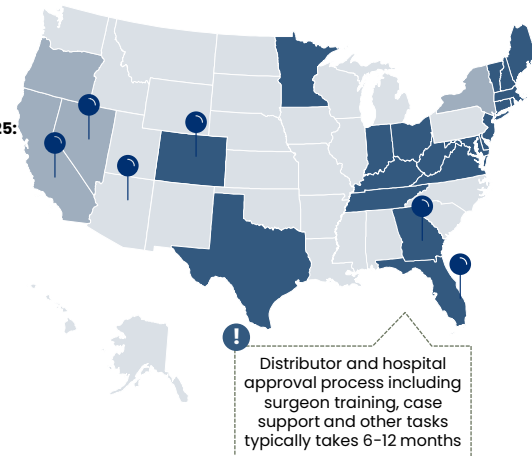
- **In March 2023, the FDA granted market authorization for the RemeOs trauma screw in the US**
- A controlled launch of the RemeOs trauma screws began in September 2023
- The next step involves initiating a broader commercialisation phase in the US, including strengthening the distribution network
- Additionally, the RemeOs screw product line will be expanded through the 510K process
- Real-world data from EU will aid in expansion of the indications
- Pass-Through-Payment¹ application process for reimbursement ongoing as a result of Breakthrough Designation status for RemeOs
- **Go-to-market underway, with continued efforts to expand the sales network during 2025**

Distribution network & conferences in the US

- Distributor agreement in place
- Distribution agreement in process
- CONFERENCE ATTENDANCE 2025

Bioretec conference attendance 2025:

- AAOS in San Diego, California
- ACFAS in Phoenix, Arizona
- POSNA in Las Vegas, Nevada
- AOFAS in Savannah, Georgia
- NASS in Denver, Colorado
- IPOS in Orlando, Florida



Note: 1) Pass-through-payment is a US reimbursement pathway used to compensate hospitals and surgeons for the usage of innovative medical technologies not yet fully covered by standard Medicare rates

CE-mark approval in EU will accelerate global RemeOs adoption

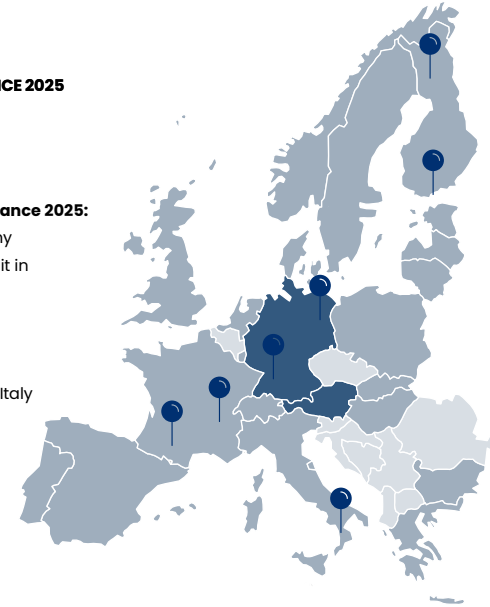
- **CE mark received for the RemeOs Trauma Screw product portfolio in January 2025**
- The product portfolio will be launched in Europe through a focused market approach
- Existing direct sales and partner distribution network will be utilized in Europe and other CE recognizing countries
- Launch in each country still requires notifying local authorities, as well as distributor training and education, causing some “lag” in sales
- Commercialization of the product in Europe also benefits US FDA approvals via real-world clinical data
- **Gradual ramp-up of RemeOs sales expected from Q2/2025 onwards**

Distribution network & conferences in Europe

- Direct sales
- Distribution partner
- CONFERENCE ATTENDANCE 2025

Bioretec conference attendance 2025:

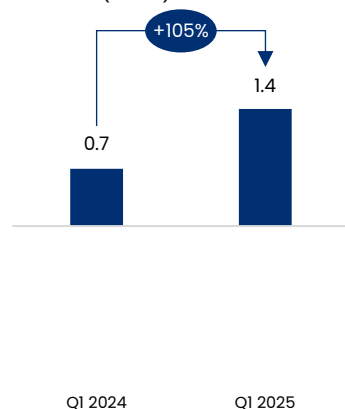
- KKOU in Stuttgart, Germany
- Finnish Orthopedic Summit in Lapland, Finland
- EPOS in Toulouse, France
- EFORT in Lyon, France
- ICTTP in Helsinki, Finland
- Biometal 2025 in Cetraro, Italy
- DKOU in Berlin, Germany



Q1 update – Ramping up for sustainable growth

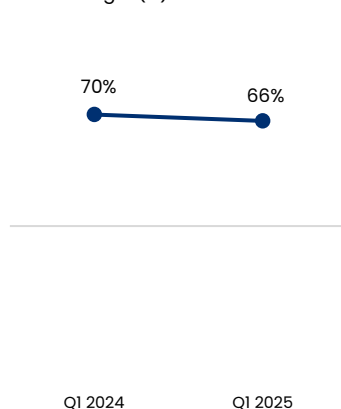
Update on Q1 results

Net sales (EURm)



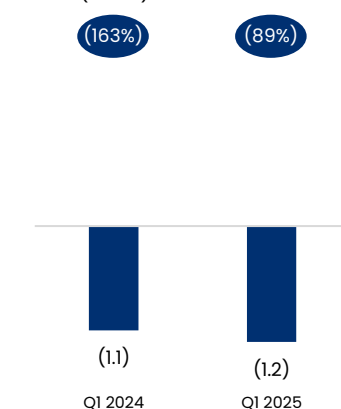
- Net sales over doubled YoY, increasing by 105%
- Significant majority of sales came from Activa in Asia
- RemeOs phase two – expansion from controlled launch ongoing, not reflected in sales yet

Sales margin (%)



- Sales margin slightly decreased YoY, dropping from 70% to 66%
- Decrease driven by higher share of sales in Asia (lower margins than in the US)

EBITDA (EURm)



- EBITDA decreased by EUR 0.1m compared to Q1 2024
- EBITDA-% increased from (163%) to (89%)

Key operational milestones

- The CE-mark with wide-ranging indications for both adults and pediatrics enables the collection of real-world data, supporting expansion efforts in the U.S. market
- Achieved highest quarterly manufacturing output to date
- Accelerated U.S. market access with the signing of eight new distributors in a single quarter, enhancing commercial reach

Growing global interest with gradual operational ramp-up ongoing



Appointment of the
new Interim CEO



Transition from an
R&D-focused
organization to a
commercially oriented
and globally operating
company



Leverage CE-mark for
global growth



Continue to expand
the U.S. distribution
network and focus on
strong sales growth

RemeOs™

Attain broader product
range FDA approval for
RemeOs in the U.S.

Key investment highlights

1

Innovative implant technology aiming to improve patient outcomes

- World's first and only FDA-approved absorbable metal implants
- Eliminates the need for unnecessary removal surgeries, reduces infection risk, and promotes faster recovery
- Patented magnesium alloy material, hybrid composite material, and manufacturing of such devices

2

\$10B+ market opportunity

- Total addressable market of \$10B+ with demand for innovative & cost-saving solutions
- Rapid forecasted adoption of absorbables; usage in just Trauma Screws to grow almost 10% p.a. until 2033

3

All set for accelerated growth – CE mark obtained

- Supported by clinical data, scalable manufacturing, regulatory authorisations (FDA, CE), and surgeon approval
- Established sales network with presence in 40 countries already

4

Clear growth strategy to execute commercialization plan

- Carefully planned launch of RemeOs ongoing in the United States and Europe
- Management team with extensive experience from MedTech industry
- Trauma Screws 2023-; DrillPins 2025-; Staples 2026-; Plates 2027-; IM-Nails 2028-; Spinal Cage 2028-


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Our vision is a purer world where
technology and biology naturally
merge to make healing solutions safer,
more reliable and universally
accessible

Thank you.

Appendix

Management team



Sarah van Hellenberg Hubar-Fisher
Interim CEO

At Bioretec since 2021
Previous experience:

Johnson & Johnson
Novartis
Global



Johanna Salko
CFO

At Bioretec since 2021
Previous experience:


Salcomp
Arthur Andersen
EY



Timo Lehtonen
CTO (former CEO)

At Bioretec since 2019
Previous experience:

Skela
INCON
ABM Composite



Rami Ojala
Sales & marketing director

At Bioretec since 2022
Previous experience:

Medtronic
TERUMO



Mari Ruotsalainen
Director QA & RA

At Bioretec since 2004
Previous experience:


Molnlycke
CONMED



Esa Hallinen
Director of Operations

At Bioretec since 2023
Previous experience:

ABM Composite
Schering
WIPAK



Frank Sarcone
VP of US sales

At Bioretec since 2024
Previous experience:

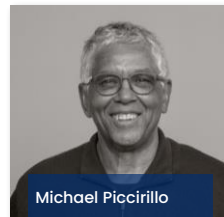
stryker
ArthroX

Board of Directors





Kustaa Poutainen
Chair of the Board

Bioretec board since 2023
Previous experience:

Michael Piccirillo

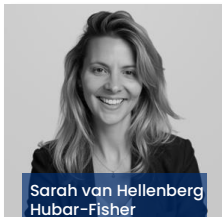
Bioretec board since 2018
Previous experience:

Päivi Malinen


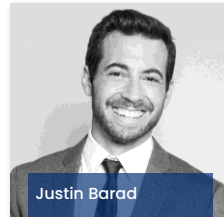
Bioretec board since 2022
Previous experience:

SPRINGVEST




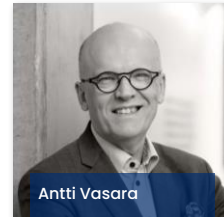
**Sarah van Hellenberg
Hubar-Fisher**

Bioretec board since 2021
Previous experience:


Justin Barad

Bioretec board since 2025
Previous experience:

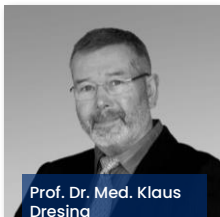



Antti Vasara

Bioretec board since 2025
Previous experience:



Scientific Advisory Board (SAB)



**Prof. Dr. Med. Klaus
Dresing**

Chairman since 2021

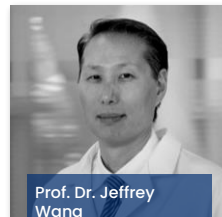
Chairman of the AO
Alumni Association,
member of the AO Trauma
International Board



Prof. Dr. Fan Liu

Member of SAB since 2021

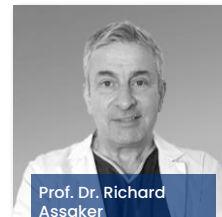
Chief and Professor in
Department of Orthopedic
Surgery, Affiliated Hospital
to Nantong University



**Prof. Dr. Jeffrey
Wang**

Member of SAB since 2023

Professor of Orthopaedic
Surgery and Neurosurgery,
the Keck School of
Medicine at USC



**Prof. Dr. Richard
Assaker**

Member of SAB since 2023

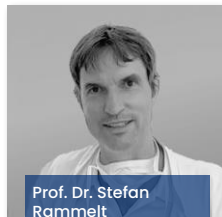
Professor in Neurosurgery,
Hopital Roger Salengro,
Lille



Dr. Robert Leland

Member of SAB since 2023

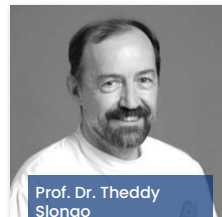
Clinical Assistant Professor
in the Department of
Orthopedics at the
University of Colorado



**Prof. Dr. Stefan
Rammelt**

Member of SAB since 2023

Professor of Trauma &
Reconstructive Surgery,
Head, Foot & Ankle Center,
University Hospital,
Dresden



**Prof. Dr. Theddy
Slongo**

Member of SAB since 2023

Head of Pediatric Surgery
and Child Traumatology,
Children's Clinic, Bern



Dr. Verena Schreiber

Member of SAB since 2023

Pediatric Orthopaedic
Surgeon, Nicklaus
Children's Hospital
Orthopedic, Sports Health,
and Spine Institute, Miami