

**bioretec**

**Bioretec Ltd  
Annual Report**

**2023**

**Danske Bank  
Small & Mid Cap  
Seminar**



THURSDAY 14<sup>TH</sup> 2024

# BIORETEC IN BRIEF

## Pioneer in biodegradable orthopedic implants and reformer of surgical treatment

Bioretec is headquartered in Tampere, Finland, and has subsidiaries in Austria and the United States.

- The company's share is listed on Nasdaq First North Growth Market Finland.
- At the end of 2023, the company employed 37 professionals

Bioretec products are sold worldwide in approximately 40 countries.

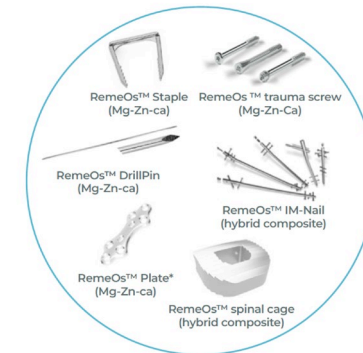
- The main target market is the U.S. and the majority of Bioretec's revenue is generated from exports, with 99% coming from outside Finland in 2023.
- Bioretec's products are sold through the company's distributor network.

Product technology is built on our expertise in merging materials science and biology for active implants that promote bone growth and healing.

- RemeOs™ product line uses advanced next-generation materials based on magnesium alloy for improved implant strength and osteopromotive properties.
- Activa line includes self-reinforced biodegradable polymer products for various surgical applications.

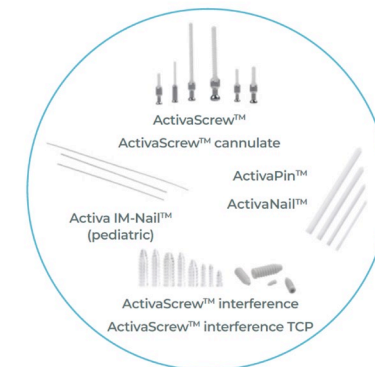
The RemeOs™ and Activa implants are designed to obviate the need for removal surgery, facilitating the healing process, reducing healthcare costs, and enhancing patient wellbeing.

### RemeOs™ product pipeline



✓ Manufactured from RemeOs™ alloy<sup>2</sup> and patented hybrid composite<sup>3</sup>

### Activa product pipeline



✓ Manufactured of self-reinforced biodegradable polymer (PLGA)



# BIORETEC IN BRIEF

## Bioretec's goal is to improve patients' quality of life and provide significant benefits to patients, the healthcare system and society

### Benefits for the patient

Patient avoids:

- implant removal surgery and subsequent recovery.
- the risks of complications typically associated with it, such as nerve damage, inflammation and refracture.
- hospitalization, sick leave and possible loss of income associated with the implant removal surgery.
- Because the RemeOs™ products contain only natural elements essential for bone growth, the patient avoids long-term effects caused by the foreign materials in the body.

### Benefits for the healthcare unit

Surgeons can:

- focus on value-added primary operations rather than on removal surgeries.
- use and surgical methods are consistent with traditional metal implants.
- use magnetic resonance imaging (MRI) unlike with traditional titanium and steel implants.

### Benefits for society

Society and the healthcare system receives:

- more efficient use of resources to reduce the overall cost of operations when no removal is needed and lost productivity.
- fewer operations to reduce staffing shortages and waiting times for treatments.
- In a country the size of Germany, the implant removal costs have been calculated to be more than EUR 1 billion per year<sup>1</sup>.



1) Source: Destatis, Robert Koch Institute, Federal Health Report, refers to year 2014

# HIGHLIGHTS OF THE YEAR

## Another year in a desired growth trajectory

### March: U.S. market authorization for the RemeOs™ trauma screw

We received a De Novo market authorization from the US Food and Drug Administration (FDA) for our biodegradable RemeOs™ trauma screw. This was the world's first U.S. market authorization for biodegradable metal product, which also created a new FDA product classification to the U.S.



### April: Updated product range and financial targets as well as share issue

We expanded our product portfolio to better meet demand, refined our market strategy in the United States and updated our financial targets. We also successfully carried out a directed share issue in which we raised EUR 10 million.



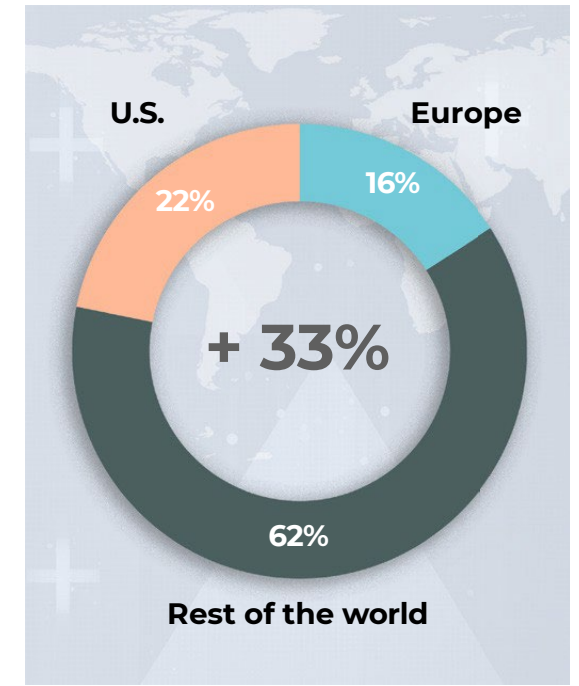
### September: RemeOs™ trauma screw distribution agreement for the U.S. market

We signed a distribution agreement for the U.S. market with Spartan Medical for RemeOs™ screws. Deliveries to the United States began in the fourth quarter of the year.



### Full year: Net sales increased significantly again

Our net sales grew by 33 percent from EUR 2.9 million to EUR 3.9 million. Of the net sales, 16% came from Europe, 22% from the United States and 62% from the rest of the world.





# HIGHLIGHTS OF THE YEAR

## Year 2023 in numbers

**EUR 3.9 M**

(EUR 2.9 M)

Net sales

**EUR 2.8 M**

(EUR 2.1 M)

Sales margin

**71.9%**

(72.7%)

Sales margin, %  
of net sales

**EUR -2.8 M**

(EUR -2.1 M)

EBITDA

**37**

(28)

Employees at  
end of year

**25.6%**

(28.1%)

Share of R&D  
spend on  
total costs

**8** registered product families  
(FDA or CE-marked)

**~250** implants  
in portfolio

Products sold  
in **~40** countries

**>35,000** surgical  
operations in 2023

# REMEOS™ IN THE U.S. MARKET

## RemeOs™ controlled launch ongoing with a phased approach

### The focus for the initial rollout is to build product confidence among leading surgeons.

- Gathering real-world clinical evidence from Post-Market Surveillance (PMS) for Marketing and additional value dossiers for private insurance.
- Conducted in collaboration with Key Opinion Leaders (KOLs), academic centers, and clinical professionals
- Gradual sales increase is expected as the market recognizes product benefits.

### Deliveries of RemeOs™ screws started in Q4 2023.

- Hospital approval processes are ongoing as the sales process to access Ambulatory Surgery Centers (ASC) and small private hospitals takes around 3-6 months and Integrated Delivery Networks (IDNs) 6-10 months

### First surgeries with RemeOs™ screws already completed.

- Launch supported by Ankle and Specialist of the Scientific Advisory Board

### CONTROLLED LAUNCH STRATEGY WITH SPARTAN MEDICAL

- 1. Strategic control and alignment:** Bioretec maintains oversight of product positioning and market targeting, ensuring a focused introduction in the initial phase. The launch strategy differentiates between the civilian segment, targeting a select number of academic and trauma centers, and the DoD/VA segment, utilizing Spartan's established networks.
- 2. Access to critical data:** The strategy provides Bioretec with valuable insights into customer usage patterns, surgeon community feedback, and patient experience, facilitating informed decision-making and strategy refinement.
- 3. Expertise in new market development:** Bioretec has engaged product specialists, known for their market development expertise, lead distributor training and sales activities, ensuring that healthcare professionals receive comprehensive education on the product's benefits.
- 4. Education and training:** Bioretec designs and implements the education and training program to ensure that surgeons and healthcare professionals have a comprehensive understanding of the product's benefits.



# SCIENTIFIC ADVISORY BOARD

## Leading experts supporting throughout the lifecycle of products



SAB 2023 ANNUAL MEETING AND WORKSHOP AT TURKU, FINLAND 14-16.9. 2024

A key component of Bioretec's development strategy is the invaluable guidance and support of leading experts in the field. The role of Bioretec's Scientific Advisory Board (SAB) is to support Bioretec's operations throughout the life cycle of products, from early-stage concepts through product development to commercialization

and continuous product support. The SAB acts as a channel to key opinion leaders, experienced surgeons who act as trendsetters in the introduction of new technologies in their areas of expertise. In addition to specific topic meetings with certain members of the team, Bioretec has regular quarterly and annual meetings with the entire SAB.

### Trauma advisors



**Prof. Dr. Klaus Dresing, Germany**

**Chairman of the SAB since 2021**  
Chairman of the AO Alumni Association, member of the AO Trauma International Board



**Prof. Dr. Fan Liu, China**

**Member of the SAB since 2021**  
Vice President, Chief and Professor in Department of Orthopedic Surgery, Affiliated Hospital to Nantong University

### Pediatric advisors



**Prof. Dr. Theddy Slongo, Switzerland**

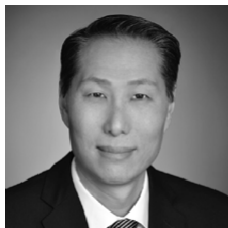
**Member of the SAB since 2023**  
Head of Pediatric Surgery and Child Traumatology, Children's Clinic, Bern



**Dr. Verena Schreiber, USA**

**Member of the SAB since 2023**  
Pediatric Orthopaedic Surgeon, Nicklaus Children's Hospital Orthopedic, Sports Health, and Spine Institute in Miami

### Spine advisors



**Prof. Dr. Jeffrey Wang, USA**

**Member of the SAB since 2023**  
Professor of Orthopaedic Surgery and Neurosurgery, the Keck School of Medicine at the University of Southern California (USC)



**Prof. Dr. Richard Assaker, France**

**Member of the SAB since 2023**  
Professor in Neurosurgery, Hopital Roger Salengro, Lille

### Ankle and foot advisors



**Prof. Dr. Stefan Rammelt, Germany**

**Member of the SAB since 2023**  
Professor of Trauma & Reconstructive Surgery, Head, Foot & Ankle Center, University Hospital, Dresden



**Dr. Robert Leland, USA**

**Member of the SAB since 2023**  
Clinical Assistant Professor in the Department of Orthopedics at the University of Colorado

## Focus areas in 2024

Increasing the awareness, usage, and clinical experience with RemeOs™ screws in the U.S.

- Expansion of the RemeOs™ screw product line and indications in the U.S

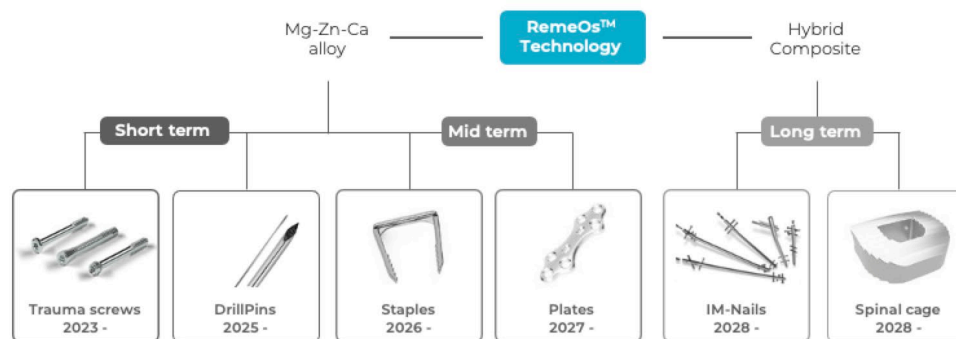
Receiving the CE mark for the RemeOs™ screws in the second quarter of 2024

- Starting the roll-out of the RemeOs™ screws in Europe through the existing distribution network

The ramp-up of RemeOs™ production capabilities.

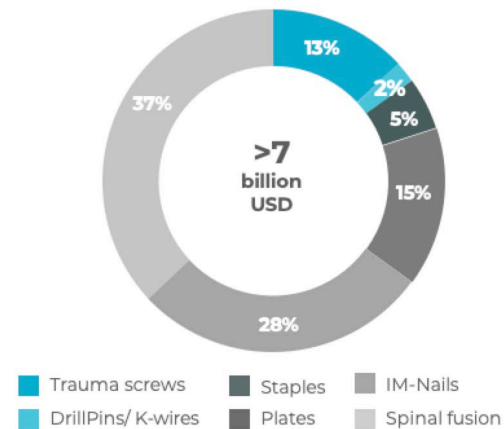
Conducting preclinical and clinical trials with RemeOs™ pipeline products

RemeOs™ Product Group Pipeline



Estimation of commercialization of each group's first products. Possible anatomical locations and final indication of RemeOs™ products depend on regulatory approval in connection with each product's marketing authorization

Total addressable market for Bioretect's products





# BIORETEC AS AN INVESTMENT

1

**Attractive market** – global total addressable market of ~USD 7 billion with increasing demand for orthopaedic implants

2

**Superior solution for patient healing** – magnesium-based biodegradable implants promote bone healing and eliminate need for implant removal

3

**The first biodegradable\* metal product group authorized in the US**

4

**Strong pipeline for launching additional products in coming years**  
– the market authorization paves the way for next products

5

**Experienced management team executing commercialisation plan**  
– supported by top-quality SAB

\*In this release the term (bio)degradable is interchangeable with (bio)absorbable and (bio)resorbable





# bioretec

*better healing – better life*

## **Financial reporting in 2024**

In 2024, Bioretec will publish the following financial reports:

business review for January–March 2024 on  
Thursday 16 May 2024

half-year report for January–June 2024 on  
Thursday 15 August 2024

business review for January–September  
2024 on Thursday 14 November 2024

## **Annual General Meeting**

Bioretec's Annual General Meeting is planned to be held on Friday, 26 April 2024. Bioretec's Board of Directors will convene the Annual General Meeting separately at a later date.

Financial reports will be available on the company's website, once they are published, at [www.bioretec.com/investors](http://www.bioretec.com/investors). The company's releases can be subscribed using the form available on the website. Bioretec maintains a 30-day silent period in its investor and media contacts prior to the publication of its financial statements bulletins and half-year reports.

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[www.bioretec.com](http://www.bioretec.com)

# MANAGEMENT TEAM

## Management Team on 31 December 2023



**Timo Lehtonen**

CEO since 2019



**Johanna Salko**

CFO since 2021



**Kimmo Lähteenkorva**

CTO since 2017



**Esa Hallinen**

Director of Operations  
since 2023



**Rami Ojala**

Sales and Marketing Director  
since 2022



**Mari Ruotsalainen**

Director, QA & RA  
since 2018



**Minna Ahlstedt-Soini**

Production Director  
since 2015



More detailed CV information:

<https://bioretec.com/investors/investors-in-english/governance/management-team>



# BOARD OF DIRECTORS

## Board of Directors on 31 December 2023



**Tomi Numminen**

Chairman of the Board of Directors since 2019, Member of the Board since 2016\*  
Professional board member



**Michael Piccirillo**

Member of the Board since 2018\*\*  
Managing Director, VALUGEN GmbH



**Pekka Simula**

Member of the Board since 2020\*\*  
Partner, Innovestor



**Sarah van Hellenberg Hubar-Fisher**

Member of the Board since 2021\*

Healthcare industry professional, board member and venture leader



**Päivi Malinen**

Member of the Board since 2022\*

Laissa Oy, business partner



**Kustaa Poutiainen**

Member of the Board since 2023\*\*

President and Chairman of the Board, Stephen Industries Inc Oy



More detailed CV information:  
<https://bioretec.com/investors/investors-in-english/governance/board-of-directors>

\*Audit committee  
\*\*Remuneration and nomination committee