Business Review January-March 2025 (unaudited)

Q1 Strong net sales in the first quarter; CE approval with comprehensive indications received in January accelerates the future expansion of RemeOs products

JANUARY–MARCH 2025 IN BRIEF

- In January, Bioretec's RemeOs™ trauma screw product family received comprehensive CE approval, allowing market launch in Europe and non-European countries that recognize the CE mark.
- Commercialization efforts progressed with several new distribution agreements signed in the U.S.
- The new CE-marked RemeOs products are being transferred into production, and preparations are continuing to increase the manufacturing capacity and ramp up their production.
- Net sales amounted to EUR 1,396 thousand (1–3/2024: EUR 682 thousand). The increase was achieved due to strong sales to China. Scheduling Activa orders for the first quarter allows more resources to be dedicated to RemeOs for the remainder of the year.
- The sales margin (excl. other income) was EUR 822 (418) thousand, or 58.9% (61.3%) of net sales. The sales margin was slightly lower due to the increased share of sales to China in the first quarter, where the volume-based procurement policies continued to impact the pricing. Furthermore, the sales margin in the comparison period was suppressed by the planned production shutdown related to the ramp-up of new production capacity.
- EBITDA was EUR -1,236 (-1,112) thousand. EBITDA was burdened by increased personnel costs due to headcount growth and additional fixed costs relating to commercialization and R&D projects.
- The result for the reporting period amounted to EUR -1,298 (-1,097) thousand.

This business review is unaudited.

EUR 1,000, unless otherwise noted	1–3/2025	1–3/2024	Change, %	1–12/2024
Net sales	**1,396**	682	104.7%	**4,544**
Sales margin	**921**	478	92.6%	**3,391**
Sales margin (excl. other income)	**822**	418	96.7%	**3,221**
Sales margin, % of net sales	**65.9%**	70.1%		**74.6%**
Sales margin% (excl. other income)	**58.9%**	61.3%		**70.9%**
EBITDA	**-1,236**	-1,112	11.2%	**-4,053**
EBIT	**-1,287**	-1,139	13.0%	**-4,202**
Profit/-loss for the period (+/-)	**-1,298**	-1,097	18.3%	**-4,614**
R&D expenditure, % of net sales	**45.7%**	61.3%		**48.0%**
Equity ratio, %	**82.2%**	74.3%		**84.9%**
Cash and cash equivalents at the end of the period	**4,424**	5,981	-26.0%	**6,289**
Personnel at the end of the period	**48**	39	23.1%	**47**

KEY EVENTS IN THE REPORTING PERIOD

- In January, Bioretec's RemeOs™ trauma screw product family received comprehensive CE approval, allowing market launch in Europe and non-European countries that recognize the CE mark. The approval covers all cannulated and non-cannulated product designs with sizes ranging from 2.0 mm to 4.0 mm in diameter and 8 mm to 50 mm in length. Approved indications include the use of screws in fracture and malalignment fixations in the upper and lower extremities of adult and pediatric patients, excluding the small bones in the hand and forefoot.

CHAIR OF THE BOARD'S COMMENTS

Ramping up for sustainable growth

The first quarter of 2025 marked a pivotal phase in our commercialization journey, setting the stage for accelerated global growth. High volume orders from China contributed significantly to topline performance, reflecting both customer confidence and our readiness to scale. At the same time, we achieved record production output and signed the highest number of new U.S. distribution agreements in a single quarter, further expanding our commercial footprint. Amid macroeconomic uncertainty, the differentiated clinical and economic value of our RemeOs™ bioabsorbable implants continues to set us apart.

Net sales in the first quarter of 2025 reached EUR 1.4 million—up by 105 per cent from the previous year. Growth was primarily driven by the Activa product line sales in China, supported by our broad portfolio and established customer base. Momentum is accelerating for a successful U.S. rollout of RemeOs, with early clinical adoption, expanding distributor coverage, and growing surgeon interest validating market demand.

Our U.S. expansion gained momentum by signing eight new distribution agreements in the quarter, now spanning 14 states and more than 80 representatives. These partners were carefully selected to cover major metropolitan areas with dense hospital networks and high surgical volumes. In parallel, the Activa product line continues its successful introduction into the U.S. market. To further support adoption, we are preparing to launch a line of single-use instruments in the second half of 2025 – an essential step in addressing efficiency and safety demands in high-volume surgical environments.

The CE mark approval for RemeOs™ Trauma Screws received in January enables immediate commercialization in Europe and other CE-recognizing markets, unlocking significant new opportunities. The CE mark encompasses all implant designs and a broad range of indications. It enables immediate European launch and lays the foundation for real-world clinical data collection, which will support both local market expansion and broader U.S. indication expansions. We are actively onboarding and training our distributor and direct sales teams across Europe, with early commercial activity already underway.

On the innovation front, we continued to advance our pipeline. The RemeOs Spinal Interbody Cage program achieved a key milestone with successful large-animal proof-of-concept implantations. The RemeOs DrillPin study has initiated site selection and training to commence patient enrollment. In the U.S., the 510(k) process for our cannulated screw is progressing, while the CE-approved RemeOs line has entered post-market clinical follow-up (PMCF) trials in adult and pediatric cases across upper and lower extremities. We also started developing single-use instruments tailored to the US customer needs.

Manufacturing capacity will be further increased in the coming months, with the scaling-up of the production of the RemeOs portfolio already underway. To support the next phase of commercialization, product development, and clinical validation, we contemplate launching a new funding round by the third quarter of this year at the latest.

While global headwinds persist, we remain confident and focused on our strategy and execution. With the CE mark approval secured and momentum building across key markets, we are well-positioned to deliver growth and long-term value.

Kustaa Poutiainen, Chair of the Board

KEY EVENTS AFTER THE REPORTING PERIOD

- On May 8, the Board of Directors of Bioretec Ltd announced that the company's CEO, Alan Donze, will resign from his position and will remain available for the company until July 7, 2025. The Board of Directors will immediately initiate the process of recruiting a new CEO.

COMMERCIALIZATION STATUS

Milestones achieved:

- RemeOs™ Trauma Screw received FDA approval in the U.S. in March 2023. Bioretec announced 100% healing rate with the patients treated during the initial focused product launch phase of RemeOs™ Trauma Screw in the U.S. in June 2024.
- In 2024, Bioretec strengthened its marketing and sales experience and know-how by appointing key leaders in the U.S. and Europe.
- In January 2025, Bioretec received a comprehensive CE mark approval for RemeOs products, allowing market launch in Europe and non-European countries that recognize the CE mark.
- To support direct sales of both RemOs and Activa products, Bioretec has entered into new distribution agreements in the U.S. in the past few months covering currently 14 states with over 80 individual representatives. Earlier in 2024, Bioretec entered into logistics agreements both in the U.S. and Europe to ensure seamless operations and customer service support in both continents.
- Bioretec commenced the development of single-use instrumentation for the RemeOs and Activa products, which is favored in the U.S market due to its efficiency and risk mitigation.

Next steps:

- First RemeOs screws to be shipped to distributors and hospitals in Europe, and first surgeries with RemeOs products to be performed in Europe.
- Bioretec shall further strengthen the commercialization efforts of both the RemeOs and Activa products in the
- U.S. by entering into additional local sales and distribution agreements with partners acting as agents.
- To keep up with the growth and future potential, Bioretec will further scale up the manufacturing capacity and focus on building excellence in sales and marketing capabilities. The company plans to capitalize on the broad indication coverage of the CE mark and collect real-world clinical evidence in order to expand indications in the U.S., where current approvals are more limited.
- In the U.S., a FDA 510(k)-registration application process to widen the product range of the RemeOs Trauma Screw is ongoing.
- Preparing to launch the first single-use instrumentation sets for the RemeOs and Activa products in the second half of 2025.

FINANCIAL REPORTING IN 2025

In 2025, Bioretec will publish the following financial reports:

- half-year report for January–June 2025 on Thursday 14 August 2025
- business review for January–September 2025 on Thursday 13 November 2025

Tampere, 15 May 2025

Board of Directors

Bioretec Ltd

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Information about Bioretec

Bioretec is a globally operating Finnish medical device company that continues to pioneer the application of absorbable orthopedic implants. The company has built unique competencies in the biological interface of active implants to enhance bone growth and accelerate fracture healing after orthopedic surgery. The products developed and manufactured by Bioretec are used worldwide in approximately 40 countries.

Bioretec is commercializing and developing the new RemeOs™ product line based on a magnesium alloy and hybrid composite, introducing a new generation of strong absorbable materials for enhanced surgical outcomes. The RemeOs™ implants are absorbed and replaced by bone, which eliminates the need for removal surgery while facilitating fracture healing. The combination has the potential to make titanium implants redundant and help clinics reach their Value-Based Healthcare targets while focusing on value for patients through efficient healthcare. The first RemeOs™ product market authorization has been received in the U.S. in March 2023, and in Europe, the CE mark approval was received in January 2025. Bioretec is positioning itself to enter the addressable over USD 9 billion global orthopedic trauma and spine market and to become a game changer in surgical bone fracture treatment.

Better Healing – Better Life. www.bioretec.com