

# Q1

Business review January–March 2024 (unaudited)

## Controlled launch in the U.S. progresses

### JANUARY–MARCH 2024 IN BRIEF

- Net sales amounted to EUR 682 thousand (1–3/2023: EUR 1,071 thousand).
- The sales margin was EUR 478 (718) thousand, or 70.1% (67.0%) of net sales. The sales margin of 2024 includes other income of EUR 60 thousand accrued relating to the Business Finland grant. When excluding the grant effect, the sales margin for the current reporting period is EUR 418 thousand, or 61.3%. The main reason for the lower sales margin percentage has been the planned production shutdown due to the ramp-up of new production capacity.
- EBITDA was EUR -1,112 (-491) thousand. EBITDA was EUR -1,112 (- 491) thousand. It was burdened by increased personnel costs due to headcount growth and additional fixed costs relating to U.S. commercialization and R&D projects.
- The result for the reporting period amounted to EUR -1,097 (-557) thousand.

This business review is unaudited. This is Bioretec’s first business review for the first quarter, and comparison period figures have not been published earlier.

### KEY FIGURES

EUR 1,000 unless otherwise noted	1-3/2024	1-3/2023	Change	1-12/2023
Net sales	682	1,071	-36.4%	3,906
Sales margin	478	718	-33.4%	2,810
Sales margin, % of net sales	70.1%	67.0%		71.9%
EBITDA	-1,112	-491	126.6%	-2,833
EBIT	-1,139	-543	109.6%	-3,034
Profit/-loss for the period (+/-)	-1,097	-557	97.0%	-3,789
R&D spend on total costs, %	25.9%	24.8%		25.6%
Equity ratio, %	74.3%	44.3%		77.3%
Cash and cash equivalents at end of period	5,981	587	919.3%	6,910
Number of personnel at end of period	39	28	39.3%	37

### KEY EVENTS DURING THE REPORTING PERIOD

- European market authorization application for the RemeOs™ trauma screw proceeded to expert panel evaluation. The approval is estimated to be received during the second quarter of 2024.
- Bioretec was granted an FDA Breakthrough Device Designation status for its RemeOs™ Spinal Interbody Cage.
- Bioretec’s RemeOs™ biodegradable magnesium alloy composition was granted a patent by the U.S. Patent Office.

### CEO’S COMMENTS

#### Bioretec’s business update for the first three months of 2024

In the first quarter of 2024, our focus was on the production and distribution of our Activa product line as the U.S. market continued to utilize inventories of the RemeOs™ trauma screw from Q4 2023. Net sales this quarter were distinctly marked by contributions from different regions: Europe accounted for 27% of net sales (19% in the comparison period), the U.S. increased from 16% to 24%, while the rest of the world decreased from 65% to 49%.

The controlled launch of RemeOs™ trauma screw continued, with an evolving number of surgeries performed utilizing this innovative product. We are actively collecting and analyzing follow-up data from the surgeries to assess the efficacy of the fracture healing treated with our screws.

In preparation for continued US sales growth, the need to enhance our production capabilities resulted in a planned production shutdown In January, which is reflected in our profitability numbers for this period. This operational

enhancement included the commissioning, qualification, and ramp-up of the new CNC machine dedicated to our trauma screw line and increasing our resource allocation to operational personnel and projects, setting the stage for increased output in subsequent quarters.

Looking ahead, we are waiting to receive market authorization for the RemeOs™ trauma screws in Europe during the second quarter of 2024. Our development efforts are ongoing for the next RemeOs™ pipeline products, supported by the new RemeOs™ magnesium alloy patent and the new FDA Breakthrough Device Designation received for the Spinal Interbody Cage. Additionally, we are advancing our plans for the next U.S. market authorization and initiating the RemeOs™ DrillPin clinical study in Austria, waiting for the ethical committee and other regulatory approvals to start the First-in-Human study.

As we have concentrated on enhancing our production capabilities in the first quarter, we project that our net sales will be more heavily concentrated in the second half of the year. This strategic growth platform building has been required to expand production capabilities to serve the future anticipated market demand and product portfolio expansions.

We are grateful to our investors, customers, and personnel for their continued confidence and support. Your trust encourages our commitment to innovation and excellence as we navigate these exciting opportunities and challenges.

*Timo Lehtonen, CEO*

## **SIGNIFICANT EVENTS AFTER THE REVIEW PERIOD**

No significant events to report.

## **FINANCIAL CALENDAR IN 2024**

In 2024, Bioretec will publish the following financial reports:

- half-year report for January-June 2024 on Thursday 15 August 2024
- business review for January-September on Thursday 14 November 2024

Tampere, 16 May 2024

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 biodegradable 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 developing the new RemeOs™ product line based on a magnesium alloy and hybrid composite, introducing a new generation of strong biodegradable materials for enhanced surgical outcomes. The RemeOs™ implants are resorbed 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 is expected to be received during the second quarter of 2024. Bioretec is positioning itself to enter the addressable USD 7 billion global orthopedic trauma market and become a game changer in surgical bone fracture treatment.

Better healing – Better life. [www.bioretec.com](http://www.bioretec.com)