Q3

Business review January–September 2024 (unaudited)

Launch of the RemeOs™ Trauma Screw in the U.S. is proceeding to the next phase, EU authorization in the final stage

JULY–SEPTEMBER 2024 IN BRIEF

- Net sales amounted to EUR 685 thousand (7–9/2023: EUR 483 thousand).
- The sales margin (excl. other income) was EUR 499 (397) thousand, or 72.9% (82.2%). The main reasons for the lower sales margin percentage were related to the foreign currency exchange rate impacts, China's volume-based procurement policy effect, and the opening of the direct sales channel in Germany.
- The result for the reporting period amounted to EUR -1,367 (-1,013) thousand.

JANUARY–SEPTEMBER 2024 IN BRIEF

- Net sales amounted to EUR 2,746 thousand (1–9/2023: EUR 2,373 thousand).
- The sales margin (excl. other income) was EUR 1,951 (1,724) thousand, or 71.0% (72.6%). The main reasons for the lower sales margin percentage were related to the foreign currency exchange rate impacts, China's volume-based procurement policy effect, and the opening of the direct sales channel in Germany.
- EBITDA was EUR -3,217 (-2,108) thousand. EBITDA 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 -3,251 (-3,088) thousand. The result for the comparison period included the cost of financing arrangement amounting to EUR 795 thousand.

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

KEY FIGURES

EUR 1,000 unless otherwise noted	7–9/2024	7–9/2023	Change	1–9/2024	1–9/23	Change	1–12/2023
Net sales	685	483	41.9%	2,746	2,373	15.7%	3,906
Sales margin	562	415	35.3%	2,084	1,742	19.6%	2,810
Sales margin (excl. other income)	499	397	25.8%	1,951	1,724	13.2%	2,728
Sales margin, % of net sales	82.0%	86.0%		75.9%	73.4%		71.9%
Sales margin, % (excl. other income)	72.9%	82.2%		71.0%	72.6%		69.8%
EBITDA	-1,353	-978	38.2%	-3,217	-2,108	52.6%	-2,833
EBIT	-1,395	-1,029	35.5%	-3,316	-2,262	46.6%	-3,034
Profit/-loss for the period (+/-)	-1,367	-1,013	35.0%	-3,251	-3,088	5.3%	-3,789
R&D spend on total costs, %	23.1%	24.2%		24.2%	27.4%		25.6%
Equity ratio, %	73.1%	82.2%		73.1%	82.2%		77.3%
Cash and cash equivalents at the end of the period	2,377	8,483	-72.0%	2,377	8,483	-72.0%	6,910
Number of personnel at the end of the period	44	32	37.5%	44	32	37.5%	37

KEY EVENTS DURING JULY–SEPTEMBER 2024

In September 2024, the following persons were appointed to Bioretec's Shareholders' Nomination Board: Kustaa Poutiainen, Chair and Founder of Stephen Industries Inc Oy as Chair and Karoliina Lindroos, Head of Responsible Investment of Ilmarinen Mutual Pension Insurance Company and Marko Berg, Deputy Investment Officer of University of Helsinki, as members. The Chairman of the Board of Bioretec acts as an expert to the Nomination Board.

CEO'S COMMENTS

As I reflect on my first 100 days as CEO, I am both proud of the strides we have made and energized by the opportunities ahead for Bioretec. Our commitment to innovation and growth remains unwavering, and our transition into the second phase of the RemeOs™ Trauma Screw launch in the U.S. marks a pivotal moment in our strategy. Our preparations to expand the distribution of the RemeOs™ Trauma Screw from a select group of hospitals to a broader network in the U.S. are progressing alongside the necessary timelines for the U.S. 510(k) approval process for the RemeOs™ cannulated screw and other configurations. In recent months, we have developed plans to expand our U.S. distribution channels, identified key distributor partnerships, and laid the groundwork for our growth platform.

Bioretec achieved a 42% increase in net sales compared to Q3 of the previous year, primarily due to heightened demand in Asia. Although the delay of regulatory approvals for RemeOs™ has affected our H2 revenue, we are optimistic about our pent-up sales growth after receiving these approvals. In the third quarter, despite a slight dip in our sales margin influenced by China's volume-based procurement policies, we remain confident in the positive development of our U.S. and EU business profit margins.

In October, we refined our product development strategy by accelerating the advancement of the RemeOs™ Spinal Interbody Cage. The positive results from simulations and technological proofs of concept for this device have reinforced our belief in its potential to transform spinal treatment options. The market opportunity is substantial, with projections indicating that the market for the Spinal Interbody Cage could reach around EUR 2.3 billion by 2028, and the total addressable market for our proprietary magnesium alloy and hybrid composite-based applications could be approximately EUR 8.1 billion in the same timeframe.[1]

This acceleration of product development does not signify a departure from our core strategy. We remain fully committed to the RemeOs™ trauma product line and its commercialization in the U.S. and worldwide. We anticipate strong revenue growth from the second phase of the RemeOs™ Trauma Screw U.S. product launch from 2025 onwards.

The initial controlled launch of RemeOs™ Trauma Screws in the U.S. yielded excellent patient results, with a notable number of surgeries and successful post-healing follow-ups. This success lays the groundwork for entering the second phase of commercialization for RemeOs™ products in the U.S. and driving strong demand within the surgeon community.

While we wait for the first CE approval and the next U.S. market approvals, our focus will be on readiness for market demand by supporting our logistics partners, distributors, hospitals, and surgeons to immediately be prepared to incorporate RemeOs™ products in their patient procedures.

In summary, I am excited about our progress and the unique opportunities that lie ahead. Together, we are poised to solidify Bioretec's position as a leader in innovative medical solutions, and I look forward to sharing our journey with all stakeholders.

Alan Donze
CEO, Bioretec

[1)] Sources: The Orthopaedic Industry Annual Report 2022, ORTHOWORLD Inc.; management estimates GlobalData, GMInsights, UN, United States Government, Willey, Michael et al. (2016) Impact of Infection on Fracture Fixation Orthopedic Clinics, Volume 47, Issue 2, 357 – 364, https://www.businessresearchinsights.com/market-reports/cervical-interbody-fusion-cages-market-111868, https://www.alliedmarketresearch.com/interbody-fusion-cage-market, https://www.grandviewresearch.com/industry-analysis/spinal-fusion-device-market

PROGRESS IN THE COMMERCIALIZATION OF RemeOs™ TRAUMA SCREW

Completed steps:

- RemeOs™ Trauma Screw received Breakthrough Device Designation -status in the U.S. from the FDA in September 2021.
- RemeOs™ Trauma Screw application for the CE mark and market authorization in Europe was submitted to the European Notified Body in December 2021.
- RemeOs™ Trauma Screw application for marketing authorization in the U.S. was submitted to the FDA in May 2022.
- FDA granted market authorization to start the sales of RemeOs™ Trauma Screw in the U.S. in March 2023. This approval was the first market authorization granted by the FDA for a magnesium-based resorbable bone fixation implant in the U.S.
- Bioretec entered into a distribution agreement in the U.S. with Spartan Medical in September 2023. Spartan Medical is specialized in supplying medical devices for the U.S. government (military and veteran hospitals), and the distribution agreement allowed Bioretec to initiate the controlled launch phase of the commercialization of the RemeOs™ trauma screw in the U.S.
- Bioretec strengthened the marketing and sales experience and know-how especially in U.S. markets:
    - In May 2024 the company appointed Mr. Alan Donze as the CEO. Alan has a long experience in commercialization of medical devices in U.S.
    - In June 2024 the company appointed Mr. Frank Sarcone as Vice President of Sales for the USA. Frank has an extensive background in sales operations of medical devices in U.S.
- In preparation for the RemeOs™ Trauma Screw product launch in Europe, the company appointed Ms. Michaela Knigge to lead the direct sales activities in Central Europe.
- Bioretec announced 100% healing rate with the patients treated during the controlled product launch phase of RemeOs™ Trauma Screw in the U.S. in June 2024.
- In the U.S., Bioretec submitted a 510(k)-registration application for the FDA to widen the product range of the RemeOs™ Trauma Screw to increase market penetration.

Next steps:

- Bioretec shall further strengthen the operational efforts in the U.S. by entering into a new logistics agreement with a partner providing customer support service for the U.S. operations. This will enable smooth importation and distribution of implants and instrument sets to hospitals throughout the country.
- Bioretec shall also further strengthen the commercialization efforts in the U.S. by entering into new local distribution agreements to serve private hospitals as part of the next phase of the RemeOs™ Trauma Screw commercialization.
- In Europe, the company is waiting for the final approval of the Notified Body to enter the product launch phase. The company has not been given any specific timeline for the receival of the CE-mark, however, all documentation required by the Notified Body has been delivered to the authorities, and final stages of the process are ongoing.
    - The approval process in Europe has been long due to an extensive regulatory transition from MDD to MDR. All companies within the industry are suffering from the consequences of these changes in terms of prolonged handling times of new product approvals and the re-registration of old products.

SIGNIFICANT EVENTS AFTER THE REVIEW PERIOD

- Bioretec's Board of Directors updated on 4 October 2024 the company's product development strategy by accelerating the product development of the RemeOs™ Spinal Interbody Cage. In order to move into the next stages of RemeOs™ Trauma Screw commercialization processes in U:S. and in Europe and to support the acceleration of RemeOs™ Spinal Interbody Cage development, Bioretec is reviewing different financing alternatives and has engaged Danske Bank A/S, Finland Branch as a financial advisor.

- Bioretec's Board of Directors updated on 4 October 2024 Bioretec's financial targets as follows:

    - Reach net sales of EUR 65 million by the end of the year 2028 and to reach net sales in excess of EUR 100 million by the end of the year 2030 (previous target: EUR 62 million by the end of the year 2027); and

    - Reach positive cash flow from operating activities by the end of 2027 (previous target: by the end of 2026).

FINANCIAL CALENDAR IN 2025

Bioretec will publish its financial calendar for 2025 in December 2024.

Tampere, 14 November 2024

Board of Directors
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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 approval process is currently ongoing. Bioretec is positioning itself to enter the addressable over USD 9 billion global orthopedic trauma and spine market and become a game changer in surgical bone fracture treatment.

Better healing – Better life. www.bioretec.com