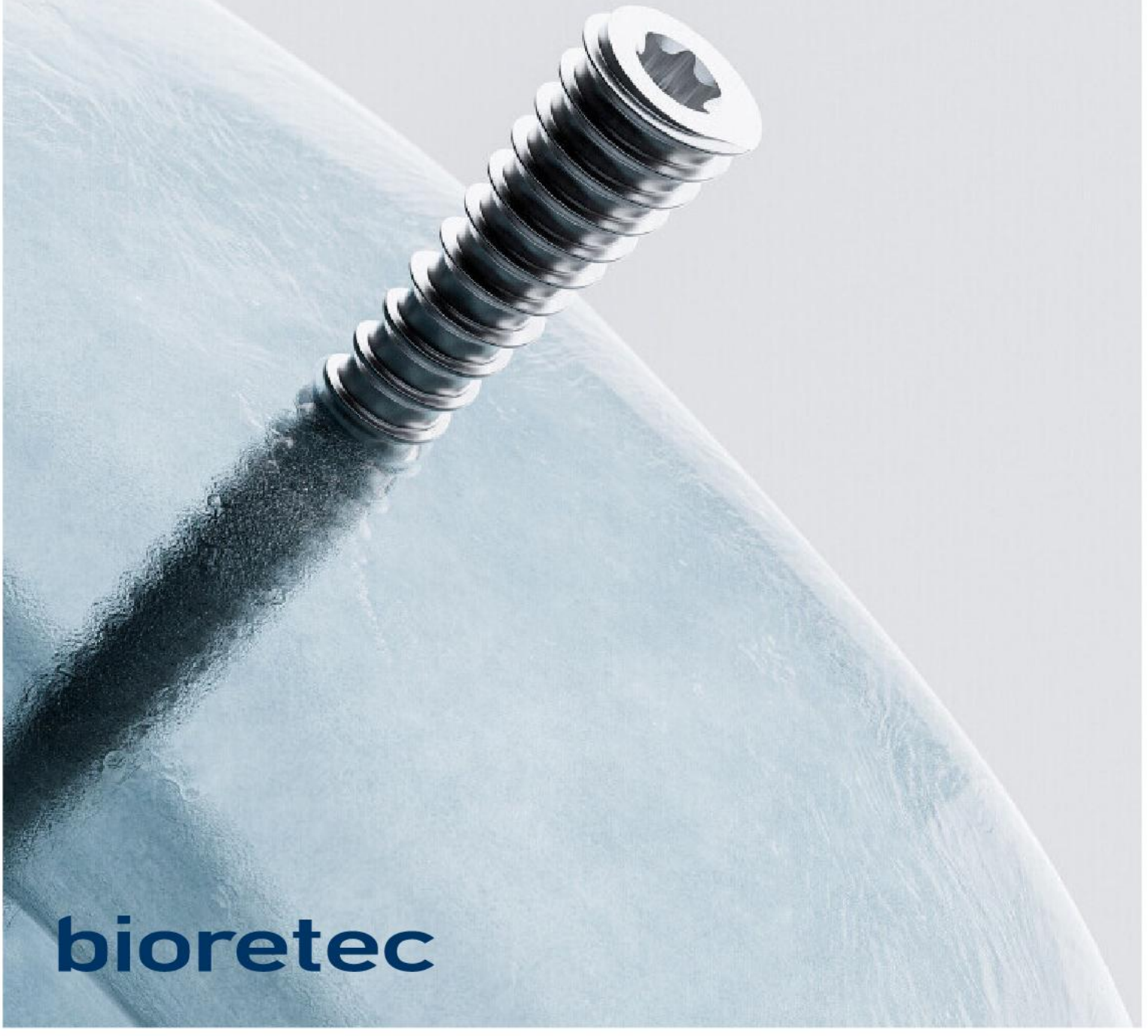
JANUARY – SEPTEMBER | **2025**

Business review



bioretec

Business review January – September 2025 (unaudited)

Q3 Strengthening commercial foundations and strategy design

JULY–SEPTEMBER 2025 IN BRIEF

- Net sales amounted to EUR 715 thousand (7–9/2024: EUR 685 thousand).
- The sales margin (excl. other income) was EUR 441 (499) thousand, or 61.6% (72.9%) of net sales.
- EBITDA was EUR -1,768 (-1,353) thousand.
- The result for the reporting period amounted to EUR -1,854 (-1,367) thousand.

JANUARY–SEPTEMBER 2025 IN BRIEF

- Net sales amounted to EUR 2,789 thousand (1–9/2024: EUR 2,746 thousand).
- The sales margin (excl. other income) was EUR 1,749 (1,951) thousand, or 62.7% (71.0%) of net sales.
- EBITDA was EUR -6,325 (-3,217) thousand.
- The result for the reporting period amounted to EUR -7,482 (-3,251) thousand.

KEY FIGURES

EUR 1,000 unless otherwise noted	7–9/2025	7–9/2024	Change	1–9/2025	1–9/2024	Change	1–12/2024
Net sales	**715**	685	4.5%	**2,789**	2,746	**1.6%**	**4,544**
Sales margin	**533**	562	-5.0%	**2,043**	2,084	**-2.0%**	**3,391**
Sales margin (excl. other income)	**441**	499	-11.7%	**1,749**	1,951	**-10.3%**	**3,221**
Sales, margin, % of net sales	**74.5%**	82.0%		**73.3%**	75.9%		**74.6%**
Sales margin, % (excl. other income)	**61.6%**	72.9%		**62.7%**	71.0%		**70.9%**
EBITDA	**-1,768**	-1,353		**-6,325**	-3,217		**-4,053**
EBIT	**-1,823**	-1,395		**-6,483**	-3,316		**-4,202**
Profit / loss for the period	**-1,854**	-1,367		**-7,482**	-3,251		**-4,614**
R&D expenditure, % of net sales	**111.2%**	66.1%		**79.9%**	47.6%		**48.0%**
Equity ratio, %	**83.7%**	73.1%		**83.7%**	73.1%		**84.9%**
Cash and cash equivalents (end of period)	**7,263**	2,377	205.5%	**7,263**	2,377	**205.5%**	**6,289**
Number of personnel (end of period)	**64**	44	45.5%	**64**	44	**45.5%**	**47**

KEY EVENTS DURING JULY–SEPTEMBER 2025

- Bioretec appointed Sarah van Hellenberg Hubar-Fisher as Chief Executive Officer on 27 August 2025. Van Hellenberg Hubar-Fisher served previously as Bioretec's interim CEO since May 2025 and as a member of the company's Board of Directors since 2021.
- Bioretec appointed René Eve as Director of Operations and as a member of the Management Team on 11 July 2025.
- Bioretec appointed Jordy Winters as Vice President of Sales Outside U.S. and as a member of the Management Team on 2 September 2025. In parallel, Rami Ojala, previously Vice President of OUS Sales, transitioned into the newly created role of Head of Global Medical Education.
- Bioretec updated the commercialization status of RemeOs™ DrillPin on 12 September 2025. Bioretec is assessing its overall commercialization strategy and pipeline, including the commercialization of the DrillPin in the U.S., and will provide an update by the end of 2025.
- Bioretec appointed Anne-Mari Matikainen as Interim Chief Financial Officer and as a member of the Management Team on 15 September 2025. The recruitment process for a new permanent CFO has been initiated.

CEO SARAH VAN HELLENBERG HUBAR-FISHER'S COMMENTS

Strengthening commercial foundations and strategy design

Almost six months have passed since I assumed my position as Bioretec's CEO. While I remain very enthusiastic about Bioretec's next phase of growth and the opportunity to lead us there, it has become increasingly evident that corrective actions and strategy adjustment are required to set us up for a clear path to success. As announced in late October, we concluded that our previous financial targets are unattainable given lengthened FDA approval timelines, our financing needs, and the planned strategic readjustment initiatives. In addition, we restated our previously reported H1/2025 figures due to incorrect accounting treatment related to past stocking distributor agreements. While these announcements were certainly unpleasant, they were necessary to clean the slate and ensure that the focus of our business is on the strength of our breakthrough technology.

The year 2025 has been, and will continue to be, a period of transition for Bioretec. With a change of both CEO and CFO, as well as the strengthening of our commercial leadership, we will continue to build market presence and to prepare for future acceleration of sales that can be only driven by clear investment in people and strategy today.

Strengthening our commercialization expertise

The biggest lesson we have learned is that our U.S. model and related growth expectations rely on the move from a stocking distribution model to direct distribution, excluding our partnership in pediatrics. It also requires an investment in local presence driven by experienced talent to ensure commercial competitiveness and success. Outside of the U.S., knowing where to focus our time and resources for optimal value is key to our performance. A full review of 'where to play' and how to execute by geography is essential for our commercial success. These adjustments in our commercialization strategy have already been initiated.

In the third quarter, we strengthened our commercialization expertise in the U.S. with the appointment of Blake Helm as VP of Sales, Area West. Blake brings more than twenty years of sales and distribution management expertise in orthopedics to Bioretec's growing U.S. presence. In addition, we increased the number of direct distribution partners in the U.S. by 7 to a total of 15 partners during the third quarter.

Outside the U.S. (OUS), we appointed Jordy Winters as Vice President of Sales (OUS). He will spearhead Bioretec's commercialization strategy outside the U.S. and advance our expansion into new markets. With nearly two decades of experience in global orthopedic commercial leadership, Jordy's expertise and international perspective will be instrumental to defining where and how we play in international markets as we continue to expand Bioretec's impact outside of the United States. Rami Ojala, previously VP of Sales (OUS), has transitioned into the newly created role, Head of Global Medical Education, developing surgeon training programs and educational initiatives to support clinical adoption of Bioretec's technologies worldwide.

Determined progress in the third quarter

While we are finalizing our new strategy, we have continued to focus on our ongoing operations. Our net sales in the third quarter prove that our Activa products are continuing to perform, whereas the breakthrough commercial impact of RemeOs™ is still underway. Our growth model for RemeOs™ is dependent on a broader portfolio of the product family (especially in the U.S.), and reliant on clear investment in training and education as well as brand and product awareness.

The third quarter represents our largest direct sales revenue in the U.S. to date. This is already an important signal of growth in the right places. Progress was further demonstrated by our October 1 announcement after the reporting period, acknowledging that the U.S. Centers for Medicare & Medicaid Services (CMS) granted our RemeOs™ Trauma Screw Transitional Pass-Through Payment (TPT) status. In addition, we closed a 3-year commercial distribution deal with OrthoPediatrics, specifically for the U.S. pediatric market in the last month of the quarter, further enhancing our distribution presence.

New strategy published by the end of the year

The end of the year marks an important stage in shaping Bioretec's future. Together with our strengthened international leadership, we will carefully consider the needed strategic readjustments in order to best position Bioretec for the journey ahead and to ensure the successful commercialization of our groundbreaking products. We will provide an update regarding our commercialization strategy and pipeline, along with revised financial targets, by the end of 2025.

At the same time, we are committed to ensuring the confidence of our shareholders and potential investors. Our reputation and reliability begin with transparent and consistent communication, an updated strategy and demonstrating our ability to execute it. I am more confident than ever that we are now on the path to do just that.

Sarah van Hellenberg Hubar-Fisher, CEO of Bioretec

KEY EVENTS AFTER THE REPORTING PERIOD

- Bioretec announced on 1 October 2025 that the RemeOs™ Trauma Screw has been granted Transitional Pass-Through Payment (TPT) status by the U.S. Centers for Medicare & Medicaid Services (CMS). The TPT payment provides hospitals and ambulatory surgical centers with additional reimbursement for new and innovative technologies. Its purpose is to cover the additional cost of new and innovative devices compared to existing treatments, thereby lowering the barrier for hospitals to adopt the RemeOs™ Trauma Screw and making it accessible to a broader patient population.
- Bioretec announced on 27 October 2025 that the company is in the process of assessing and updating its overall commercialization strategy pipeline and will be providing an update by the end of 2025. In the course of its assessment, the Board of Directors of Bioretec concluded that the financial targets published on 4 October 2024 are unattainable and will likely not be met. Accordingly, Bioretec withdrew its previously disclosed financial targets, which were to:
    - Reach net sales of EUR 65 million by the end of year 2028 and to reach net sales in excess of EUR 100 million by the end of year 2030
    - Reach positive cash flow from operating activities by the end of the year 2027.
- Bioretec announced on 27 October 2025 that it adjusts and restates previously reported H1/2025 figures and does not expect accelerated sales in 2025.
- Bioretec published the corrected H1/2025 half year report on 31 October 2025.
- Bioretec announced on 12 November 2025 that it initiates change negotiations to enhance operational efficiency and competitiveness. The negotiations will focus on Bioretec's production and marketing functions in Finland.

REMEOS™ DEVELOPMENT AND COMMERCIALIZATION STATUS

Regulatory milestones achieved:

- April 2021: The U.S. Food and Drug Administration (FDA) grants Breakthrough Device Designation for Bioretec's RemeOs™ Screw products, confirming that the product represents a breakthrough technology in traumatology and orthopedic surgery.
- December 2021: Bioretec files for CE mark for its RemeOs™ Trauma Screw. The CE mark is a legal prerequisite in order to commercialize a medical device in the European Union.
- May 2022: Bioretec submits a De Novo request for market authorization in the U.S. for its RemeOs™ Trauma Screw. The De Novo request provides a registration pathway for novel medical devices for which there is no predicate device available in the U.S. market.
- March 2023: FDA approves Bioretec's RemeOs™ Trauma Screw as the first bioresorbable metal implant in the U.S. market.
- March 2024: The FDA grants Breakthrough Device Designation for Bioretec's RemeOs™ Spinal Interbody Cage, confirming that the product represents a breakthrough technology in spinal surgery.
- January 2025: Bioretec receives CE mark approval for its RemeOs™ Trauma Screw product portfolio, allowing market launch in Europe.

Clinical highlights:

- Scientific Advisory Board (SAB) Meeting: In July, Bioretec held the annual meeting of its Scientific Advisory Board (SAB) in Stockholm. The SAB, together with members of the Board of Directors, Michael Piccirillo and Justin Barad, reviewed ongoing and forthcoming clinical trials, product pipeline progress, and technology development. The Board members were also invited to follow the SAB's progress and support its work in advancing Bioretec's scientific and clinical objectives.
- New SAB Appointment: In September, Bioretec appointed Dr. Christopher W. DiGiovanni, Professor and Chief of Foot and Ankle Surgery at Massachusetts General Hospital and Harvard Medical School, to its Scientific Advisory Board. Dr. DiGiovanni's appointment reinforces Bioretec's strategy to collaborate with globally recognized clinical leaders to guide product innovation and ensure the company's solutions meet the highest standards of safety, efficacy, and clinical relevance.
- RemeOs™ DrillPin – Hammertoe Clinical Trial: The clinical trial evaluating the RemeOs™ DrillPin in hammertoe correction is ongoing. The first patients have been enrolled and are under follow-up, with additional enrollment continuing as planned.
- RemeOs™ DrillPin – Pediatric Wrist Fracture Clinical Trial: The pediatric distal radius fracture clinical trial evaluating the RemeOs™ DrillPin has received all required authority approvals, including those from the ethics committee and national competent authority. Site initiation activities have been completed, and patient enrollment is commencing.
- RemeOs™ Trauma Screw – Post-Market Clinical Follow-Up (PMCF): The post-market clinical follow-up for the RemeOs™ Trauma Screw is ongoing, collecting cases and follow-up data of fractures and fusions from both upper and lower extremities of adult and pediatric patients. A wide range of clinical indications are already covered since the launch.

- **Training and Education initiatives:** Bioretec has initiated the development of training and education (T&E) platforms for both U.S. and international (OUS) markets. These programs aim to raise awareness of the clinical benefits and material characteristics of absorbable implant technologies and to support the broader adoption of Bioretec's RemeOs™ product family.

Next steps:

- As announced on 12 September 2025 and on 27 October 2025, Bioretec is assessing its overall commercialization strategy and pipeline, and will provide an update by the end of 2025.

FINANCIAL CALENDAR IN 2026

Bioretec will publish its financial calendar for 2026 in December 2025.

Tampere, 13 November 2025

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Bioretec Ltd

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Information about Bioretec

Bioretec is a globally operating Finnish medical device pioneer at the forefront of transforming orthopedic care with fully biodegradable implant technologies. 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's Activa product line features fully bioabsorbable orthopedic implants made from a proprietary, self-reinforced PLGA polymer. These implants deliver secure fixation through patented innovations and naturally degrade in approximately two years, eliminating the need for costly and invasive removal surgeries while supporting optimal bone regeneration. Activa products are both CE marked and FDA cleared for a wide range of indications in adult and pediatric patients.

The company's latest innovation, the RemeOs™ product line, is based on a high-performance 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 first RemeOs product market authorization was received in the U.S. in March 2023, and in Europe, the CE mark approval was received in January 2025. With the development of next-generation implants like RemeOs, Bioretec is shaping the future of orthopedic treatment, paving the way for more effective and patient-friendly solutions.

To learn more about Bioretec, visit www.bioretec.com