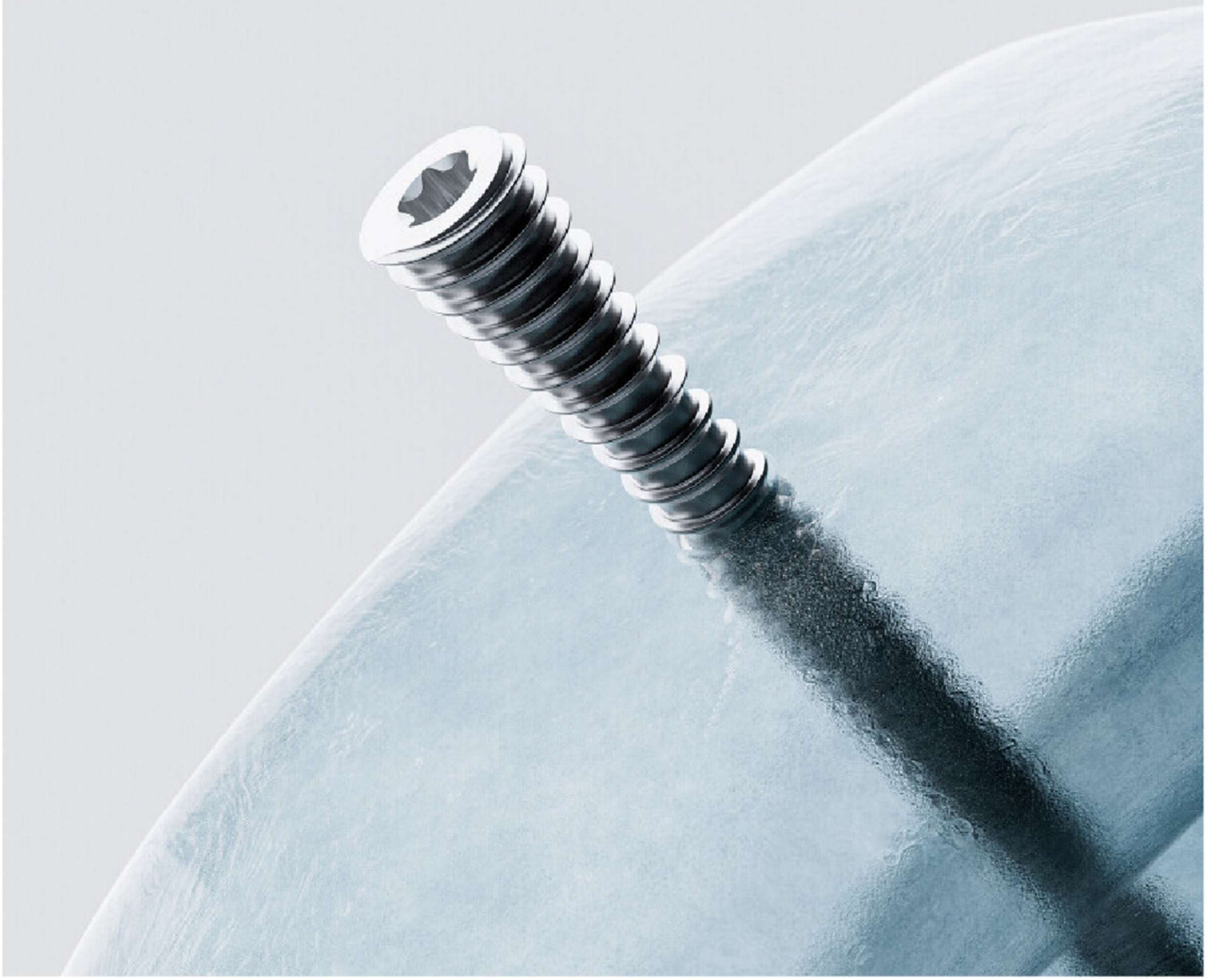
Bioretec™

Healing Beyond Absorption

Bioretec Ltd.

Business review

January–September 2026



Commercial momentum continues across key markets

July–September 2026 in brief

- Net sales amounted to EUR 1,328 thousand (7–9/2025: EUR 715 thousand)
- Adjusted sales margin was 68.7% (59.4%) of net sales
- EBITDA was EUR -1,746 (-1,768) thousand
- The result for the reporting period amounted to EUR -1,839 (-1,854) thousand

January–September 2026 in brief

- Net sales amounted to EUR 3,648 thousand (1–9/2025: EUR 2,789 thousand)
- Adjusted sales margin was 69.0% (57.5%) of net sales
- EBITDA was EUR -5,371 (-6,325) thousand
- The result for the reporting period amounted to EUR -6,517 (-7,482) thousand

Key figures

EUR 1,000 unless otherwise indicated	7–9/2026	7–9/2025	Change	1–9/2026	1–9/2025	Change	1–12/2025
Net sales	**1,328**	715	85.5%	**3,648**	2,789	30.8%	**3,522**
Adjusted sales margin, % of net sales [1]	**68.7%**	59.4%	+9.3 pp	**69.0%**	57.5%	+11.5 pp	**59.3%**
EBITDA	**-1,746**	-1,768		**-5,371**	-6,325		**-8,476**
EBIT	**-1,806**	-1,823		**-5,552**	-6,483		**-8,686**
EBIT, % of net sales	**-136.0%**	-254.7%	+118.7 pp	**-152.2%**	-232.4%	+80.2 pp	**-246.6%**
Profit / loss for the period	**-1,839**	-1,854		**-6,517**	-7,482		**-9,483**
R&D expenditure, % of net sales	**60.6%**	111.2%	-50.6 pp	**65.3%**	79.9%	-14.6 pp	**85.8%**
Equity ratio, %	**89.5%**	83.7%	+5.8 pp	**89.5%**	83.7%	+5.8 pp	**84.3%**
Return on equity, %	**-10.8%**	-14.6%	+3.8 pp	**-50.4%**	-69.6%	+19.2 pp	**-97.3%**
Cash and cash equivalents	**9,251**	7,263	27.4%	**9,251**	7,263	27.4%	**4,126**
Earnings per share (undiluted), EUR	**-0.001**	-0.06		**-0.008**	-0.28		**-0.34**
Earnings per share (diluted), EUR	**-0.001**	-0.05		**-0.004**	-0.22		**-0.28**
Number of shares at the end of the period	**1,341,785,963**	30,788,092		**1,341,785,963**	30,788,092		**30,788,092**
Number of shares at the end of the period (diluted)	**1,527,790,429**	33,821,751		**1,527,790,429**	33,821,751		**33,821,751**
Number of personnel at the end of the period	**56**	64	-12.5%	**56**	64	-12.5%	**60**

[1] From Q1/2026, the company has transitioned to reporting adjusted sales margin to be aligned with industry reporting standards. The adjusted sales margin describes the profitability of implant sales before commercialization-related expenses, such as sales commissions. Adjusted sales margin comprises the net sales of implants deducted by related cost of sales and extraordinary expenses. Items recognized below the adjusted sales margin include, among others, commissions and external services considered fixed in nature.

Net sales by geographical area

EUR 1,000	7–9/2026	7–9/2025	Change	1–9/2026	1–9/2025	Change	1–12/2025
Europe	**384**	227	69.2%	**1,162**	580	100.3%	**887**
The U.S.	**443**	183	142.7%	**1,041**	366	184.1%	**488**
Rest of the world	**501**	306	63.6%	**1,444**	1,843	-21.6%	**2,146**
Total	**1,328**	**715**	**85.5%**	**3,648**	**2,789**	**30.8%**	**3,522**

CEO Sarah van Hellenberg Hubar-Fisher's comments

Commercial momentum continues across key markets

Our commercial momentum continued in the third quarter, and net sales grew by 85.5% year-on-year to EUR 1.3 million. All geographical regions delivered strong growth during the quarter, with the U.S. continuing to achieve triple-digit growth. This performance demonstrates the impact of our focused commercial strategy, including increasing repeat surgeon utilization, strengthening our Key Opinion Leader network, and carefully selecting distribution partners in priority markets outside of the U.S. Our adjusted sales margin improved to 68.7% during the quarter, reflecting sustained improvements in the quality and mix of our net sales.

First near-term pipeline approval marks an important milestone

Our updated strategy for 2026–2028 emphasizes the expansion of our product portfolio, with the aim of introducing a new product every 12–18 months. In September, we took an important step towards delivering on this commitment as the FDA granted 510(k) clearance for our ActivaScrew™ Cannulated COM bioabsorbable compression screw. This represents the first regulatory clearance from our near-term product pipeline and supports the expansion of our offering in the U.S. market. Alongside this milestone, we continued to advance the development of our RemeOs™ product family, including ongoing clinical studies and follow-up programs aimed at strengthening clinical evidence and supporting broader adoption of our technology. Advancing our product pipeline remains a central priority, with a continued focus on disciplined execution, capital efficiency, and innovation across our absorbable implant technologies.

Strengthening our R&D leadership

Delivering on our product development ambitions requires strong R&D capabilities and specialized expertise. During the quarter, we completed an important transition in our R&D leadership. Our former CTO Timo Lehtonen assumed a new role as External Executive Advisor, continuing to contribute his extensive expertise in materials science and technology development. Conan Cavanagh joined Bioretec as Head of Research & Development in September, bringing valuable experience to strengthen our product development processes and external partnerships.

Building visibility and engagement

Throughout the year, we have continued to strengthen Bioretec's visibility and engagement with clinical and industry stakeholders through participation in key international events, including DeviceTalks Boston, the AOFAS/IFFAS 2026 Annual Meeting, LSI Europe '26 and the 18th Annual Biometal Symposium. In September, we also hosted a dedicated media day to celebrate an important commercial milestone, with cumulative global sales of Activa implants surpassing 500,000 units. This milestone demonstrates the established position of our Activa product family and sustained demand for our bioabsorbable implant technologies. The visibility activities support our efforts to increase awareness of our technologies, strengthen relationships with surgeons and industry partners, and drive broader adoption of our products.

Positioned for continued execution

The first nine months of 2026 demonstrate that our strategic priorities and commercial investments are translating into measurable progress. With continued sales momentum, an expanding product pipeline, and strengthened leadership, we are building a more scalable and commercially robust business. Looking ahead, we remain focused on setting new standards in the development and evaluation of novel absorbable technology and establishing strong market positioning through leading product performance. We also aim to build on the improvement in our margin performance during the first nine months, while expecting overall spending to remain stable and disciplined in the near term as we continue to invest in advancing our product pipeline. Our focus remains on sustaining commercial growth and delivering on our strategic priorities as we work towards establishing Bioretec as a global leader in bioabsorbable implant technologies.

Significant events in July–September 2026

- On July 2, Bioretec announced that Chief Financial Officer Tuukka Paavola will leave the company with immediate effect. The duties of the Chief Financial Officer will be assumed on an interim basis by Controller Anna-Mari Venola.
- On August 5, Bioretec announced the appointment of Panu Mikkonen (M.Sc. Econ.) as Chief Financial Officer, effective 6 October 2026. In this role, Mikkonen will report to Chief Executive Officer Sarah van Hellenberg Hubar-Fisher and will join the company's Management Team.
- On September 5, Bioretec announced that it had received FDA 510(k) clearance for its ActivaScrew™ Cannulated COM bioabsorbable compression screw. The clearance enables the commercialization of the product in the United States in accordance with its cleared indications for use.

Significant events after the reporting period

- On October 8, Bioretec announced that it initiates change negotiations to improve operational efficiency and competitiveness. The planned changes are also expected to generate annual cost savings of approximately EUR 0.3 million, supporting the company's profitability and long-term competitiveness.
- On October 12, Bioretec announced the composition of the Shareholders' Nomination Board: Tor-Oskar Karlberg from Stephen Industries Inc Oy, Rami Vehmas from Keskinäinen Eläkevakuutusyhtiö Ilmarinen and Johan Hamström from Sp-Rahastoyhtiö Oy.

Research and development

Bioretec offers two product families, Activa and RemeOs™. The Activa product family is based on self-reinforced PLGA and facilitates healing in orthopedic indications under appropriate immobilization. The RemeOs™ product family utilizes state-of-the-art absorbable metal alloy technology. RemeOs™ implants have greater load-bearing capacity than previous generations of absorbable implants and are well-suited for treating bone fractures across a wide range of indications.

Bioretec has a strong pipeline for launching additional products. The Company is especially committed to expanding the RemeOs™ family with several synergistic products in the coming years, with new types of absorbable metal alloy products already in advanced development and clinical trials.

As highlighted in the strategic priorities for 2026–2028, Bioretec plans to introduce one new product every 12–18 months and establish RemeOs™ as the leading absorbable product family and metal alloys as the preferred solution in the absorbable implant market globally.

Bioretec has divided the introduction and commercialization of new products in the pipeline into three different timeframes:

Short term (<18 months):

- Activa Headless Cannulated Screw
- RemeOs™ Trauma Screw (US portfolio expansion)
- RemeOs™ DrillPin

Medium term (18–36 months):

- Differentiated RemeOs™ absorbable trauma product(s) (e.g. elastic intramedullary nails, specialty screws, staples, anchors)

Long term (36+ months):

- RemeOs™ Spine portfolio
- RemeOs™ IM Nails
- RemeOs™ Plates

The company is not in a position to give a specific order or estimated timeline for the commercialization of individual products as this is highly dependent on regulatory approval timelines and subsequent prioritization of R&D resources.

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 a 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.
- **December 2025:** The FDA grants Breakthrough Device Designation for Bioretec's RemeOs™ DrillPin, becoming the third Breakthrough Device Designation granted to Bioretec by the FDA.
- **September 2026:** The FDA grants 510(k) clearance for its ActivaScrew™ Cannulated COM bioabsorbable compression screw. The clearance enables the commercialization of the product in the United States in accordance with its cleared indications for use.

Clinical highlights:

- RemeOs™ Trauma Screw – Post-Market Clinical Follow-Up (PMCF): PMCF activities remain underway, including ongoing case and follow-up data collection and continued onboarding of additional clinical sites. The program continues to capture fracture and fusion outcomes in both upper and lower extremities across adult and pediatric patients, covering a broad range of clinical indications. Recent follow-up results demonstrate excellent clinical outcomes and were presented at EPOS by Prof. Dr. Theddy Slongo.
- RemeOs™ DrillPin – Hammertoe Clinical Trial: The clinical trial evaluating the RemeOs™ DrillPin for hammertoe correction is ongoing. Initial patients have been enrolled and are currently in follow-up, and recruitment continues.
- RemeOs™ DrillPin – Pediatric Wrist Fracture Clinical Trial: Following completion of site initiation activities, the pediatric distal radius fracture clinical trial is ongoing and recruitment continues.
- Training and Education Initiatives: Bioretec has initiated the development of training and education (T&E) platforms for the U.S. and international (OUS) markets. These programs are designed to increase awareness of the clinical benefits and material properties of absorbable implant technologies and to support broader adoption of the RemeOs™ product family.

Financial reporting in 2027

Bioretec will publish its financial calendar for 2027 by the end of December 2026.

Tampere, November 12, 2026

Board of Directors

Bioretec Ltd.

For additional information:

Sarah van Hellenberg Hubar-Fisher
CEO
+31 6 1544 8736
sarah.hubar-fisher@bioretec.com

Panu Mikkonen
CFO
+358 50 4833 707
panu.mikkonen@bioretec.com

Certified Adviser

Nordic Certified Adviser AB, +46 70 551 67 29

Information about Bioretec

Bioretec is a globally operating Finnish medical device pioneer at the forefront of transforming orthopedic care with bioabsorbable implant technologies. The company offers two product families, Activa and RemeOs™, both based on advanced bioabsorbable materials. The products developed and manufactured by Bioretec are used worldwide in approximately 40 countries.

Bioretec's Activa product family features fully bioabsorbable orthopedic implants made from a proprietary, self-reinforced PLGA both CE marked and FDA cleared for a wide range of indications.

The company's latest innovation, the RemeOs™ product family, is based on a high-performance magnesium alloy and hybrid composite. 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. To date, the RemeOs™ product line has received three FDA Breakthrough Device Designations.

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

Bioretec™

Healing Beyond Absorption

Bioretec Ltd
Yrittäjänkulma 5
33710 Tampere, Finland
+358 20 778 9500

www.bioretec.com

