

**Bioretec™**

Healing Beyond Absorption

# Bioretec Ltd. Annual Report 2025



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*Shaping the future of  
orthopedic treatment  
and paving the way  
for more effective  
and patient-friendly  
solutions*



Bioretec's [financial statements](#) 2025  
Read more on Bioretec's [investor pages](#)

# Global pioneer in developing and manufacturing absorbable orthopedic implants

Bioretec is a globally operating Finnish medical device company leading the development and commercialization of absorbable implants focused on healing for adult and pediatric orthopedics. Our unique expertise combines materials engineering and biochemistry in active implants that promote bone growth and facilitate fracture healing after orthopedic surgery. Our operations cover the entire life cycle of the implants, from initial product design and development to commercialization and market delivery.

Bioretec offers two individual product families: **RemeOs™**, the first and only FDA market authorized absorbable and osteopromotive magnesium alloy implant with three breakthrough device designations in its product portfolio, and **Activa**, a self-reinforced PLGA derived polymer implant with

over 400,000 implants sold to date and zero reported adverse events<sup>1</sup>. Both product lines are developed and manufactured by Bioretec and sold worldwide in over 40 countries.

The RemeOs™ and Activa implants are designed to obviate the need for removal surgery and facilitate the healing process, thereby reducing healthcare costs and enhancing patient wellbeing. Our products not only offer a viable replacement for traditional metal implants but also contribute to the advancement of value-based healthcare by improving patient outcomes and operational efficiency.

**We are leading the global shift towards bioabsorbable implant technologies** – a market estimated to grow at a CAGR of >10% to over USD 4 billion by 2033.



**Our mission** is to replace permanent hardware with fully absorbable fixation that restores bone naturally – eliminating removal surgeries, reducing complications, and leaving nothing behind but healthy bone.



**Our vision** is to become the global market leader in absorbable orthopedic implants designed for optimal healing.

# Bioretec's legacy and leadership

## Legacy

Founded in 2003 in Finland by Professor Pertti Törmälä, Bioretec initially concentrated on creating next-generation biopolymer implants with controlled degradation rates and higher strength, which evolved into the Activa product line. Over the years, Bioretec transitioned its focus, leading to a strategic renewal between 2017 and 2020 aimed at addressing the evolving needs of the orthopedic industry. This period reignited product development, emphasizing the innovation of new technologies. This innovative drive culminated in the creation of RemeOs™, a revolutionary implant technology with no direct market equivalents prior to its introduction.



## Leadership

Today, Bioretec is headquartered in Tampere, Finland, with subsidiaries in Austria and the United States. Bioretec's freshly updated strategy for 2026–2028 focuses on global commercial acceleration in both the United States and markets outside of the United States (OUS), enabled by continued R&D and expansion of the RemeOs™ product family.

At the end of 2025, Bioretec employed 60 professionals. The company's shares have been listed on Nasdaq First North Growth Market Finland since 2021.

***Shaping the future of orthopedic treatment and paving the way for more effective and patient-friendly solutions***

# Strengthening Bioretec's commercial footprint and leadership



## January

### **Bioretec receives CE mark approval for its RemeOs™ Trauma Screw product portfolio**

Bioretec successfully completed its CE mark approval process of the RemeOs™ Trauma Screw product portfolio. The CE mark approval allows market launch within the European Union and in non-European countries that recognize the authorization.

[Read more →](#)

## March

### **Mirva Ekman appointed as Quality Director**

Bioretec announced the appointment of Mirva Ekman as Quality Director and member of the management team as of April 22, 2025. In this role, Ekman will oversee the company's Quality Assurance and Quality Control functions and serve as a quality function management representative to European and U.S. regulatory authorities.

[Read more →](#)

## May

### **Sarah van Hellenberg Hubar-Fisher appointed as CEO**

Bioretec announced the appointment of Sarah van Hellenberg Hubar-Fisher as interim CEO in May, and later as permanent CEO in August. Van Hellenberg Hubar-Fisher is an accomplished medtech executive and brings over 23 years of global healthcare leadership and new technology introduction experience to Bioretec.

[Read more →](#) [Read more →](#)

## June

### **Successful completion of EUR 9.2 million rights issue**

Bioretec arranged a rights issue in June. The objective of the rights issue was to strengthen Bioretec's capital structure and to ensure its ability to implement its RemeOs™ commercialization strategy. The rights issue was oversubscribed and the company raised gross proceeds of approximately EUR 9.2 million.

[Read more →](#)

## July

### **René Eve appointed as Director of Operations**

René Eve was appointed as Director of Operations and as a member of the Management Team. Eve has strong expertise in the pharmaceutical industry and mass manufacturing of metal products. He will play a key role in Bioretec's growth into the next phase of commercialization for our RemeOs™ and Activa products globally.

[Read more →](#)

# Strengthening Bioretec's commercial footprint and leadership



## September

### Jordy Winters appointed as VP of OUS Sales

Jordy Winters was appointed as Vice President of Outside U.S. (OUS) Sales and as a member of the Management Team. Winters will spearhead Bioretec's international commercial strategy, advancing the company's expansion into key markets outside the United States and driving revenue growth. In parallel, Rami Ojala transitioned into the newly created role of Head of Global Medical Education.

[Read more →](#)

## September

### Dr. Christopher W. DiGiovanni appointed to Scientific Advisory Board

Dr. DiGiovanni is an internationally recognized foot and ankle surgeon who has dedicated nearly three decades to advancing clinical care, surgical innovation, and medical education. His appointment advances Bioretec's mission to engage world-class clinical leaders to guide product innovation and ensure its solutions meet the highest standards of safety, efficacy, and real-world applicability.

[Read more →](#)

## October

### RemeOs™ Trauma Screw approved for Transitional Pass-Through Payment (TPT) in the U.S.

Bioretec was granted TPT status by the U.S. Centers for Medicare & Medicaid Services (CMS) for the RemeOs™ Trauma Screw effective October 1, 2025. The TPT payment provides hospitals and ambulatory surgical centers with additional reimbursement for new and innovative technologies. The TPT code description was revised in January 2026, aligning with the regulatory pathway under which the Trauma Screw received Breakthrough Device Designation and De Novo market authorization.

[Read more →](#)

## December

### FDA Breakthrough Device Designation status for RemeOs™ DrillPin

Breakthrough Device Designation is granted to medical devices that represent a breakthrough technology or offer significant advantages over existing approved or cleared alternatives. The designation gives Bioretec prioritized and more interactive communication with the FDA during the remaining development and review process, which is expected to support an efficient clinical and regulatory pathway for the DrillPin.

[Read more →](#)

## December

### Updated strategy and financial targets for 2026–2028

Bioretec's strategy and value creation for the next three years focuses on commercial performance and sales acceleration in both the United States and markets outside of the United States (OUS), enabled by continued R&D and expansion of the RemeOs™ product family. Bioretec's new financial targets are to reach net sales exceeding EUR 10 million by the end of the year 2028 and to maintain an average sales margin exceeding 70% during the strategy period.

[Read more →](#)

# Year 2025 in highlights

**€ 3.5M**

Net sales  
(€ 4.5M in 2024)

**65.7%**

Sales margin, % of net sales  
(70.9% in 2024)

**€ -8.5M**

EBITDA  
(€ -4.1M in 2024)

**85.8%**

R&D spend of net sales  
(48.0% in 2024)

**60**

Personnel at the end of 2025  
(47 at the end of 2024)

**~250**

Implants in portfolio

**~40**

Countries where  
products are sold



# A year of rebuilding and renewed focus

2025 was a year of transition and rebuilding. After stepping into the CEO role in May, it quickly became clear to me and the leadership team that to unlock Bioretect's full potential, we first needed to strengthen the foundation. We therefore spent the year reviewing every aspect of our operations, commercial structure, and performance to ensure a stable base, capable of supporting Bioretect's future growth. As a result of these necessary adjustments, we exit the year with a more agile commercial organization, a strengthened strategic focus, and greater readiness to execute our next phase.

Our financial results reflect a year of taking one step back to reposition for lasting progress. Absorbing significant changes in leadership roles, commercial capabilities, distribution models, and ordering cycles were investments in resilience and scalability. The deliberate transition from stocking distributors to a direct distribution model in

the United States in 2025, marks a strategic move that provides stronger transparency, predictability and long-term quality of net sales. While the financial results reflected the impact of strategic resets, they also reinforced the value of decisive action. At the same time, continued R&D momentum advanced our world class portfolio, further paving the way for sustainable topline growth.

Looking ahead, our commitment is to clarity of execution, anchored by measurable goals, data-driven accountability, and clear communication around our strategy and its developments. Despite ongoing macroeconomic headwinds, the healthcare sector remains strongly receptive to Bioretect's leading absorbable technologies focused on healing. With disciplined execution and clear objectives, Bioretect enters 2026 better aligned, more resilient, and ready to capture market opportunity.

## Commercial momentum

Commercial momentum is accelerating as we actively expand awareness of Bioretect's technology across key markets. In H2 2025, we re-established our commercial presence in high impact geographic regions where Bioretect's technology had been underrepresented. Demand for next-generation biomaterial solutions is clear—and our sharpened "where to play" strategy ensures we are targeting the right markets with precision. We now have greater insight into adoption timelines, regulatory pathways, and procurement dynamics within both the U.S. and international markets and are prepared to execute with clear intent.

Across all key geographies, we've deepened our understanding of key drivers of adoption – from pricing strategies and clinical advocacy to surgeon education and partnership



engagement – and converted those insights into actions. These foundations are already showing results: direct sales revenue in the U.S. grew for three consecutive quarters in 2025, representing commercial growth in both our Activa and RemeOs™ product families, a strong signal that our rebuilt commercial strategy and structure is poised to deliver. Outside of the U.S., the activation of key markets with new distribution partners, contractual improvements, and a full review of margin improvement opportunities, strengthens our market position and aligns with more profitable performance in the year ahead.

In addition to our world class Scientific Advisory Board, 2025 marked the establishment of our Key Opinion Leader (KOL) network in the United States, bringing fresh guidance and support for Bioretec’s commercial strategy from respected thought leaders in their field. With an energized pipeline, new product launches ahead, and a renewed go-to-market strategy in place, Bioretec enters 2026 positioned to accelerate.

### Milestones for the RemeOs™ product family

Our RemeOs™ product family achieved important milestones in 2025. The CE mark approval for the Trauma Screw in January marked a major step into commercialization for countries that recognize the CE mark. Since then, the RemeOs™ line has advanced from development to early commercial uptake, bolstered by new surgeon experiences and country-level approvals.

Regulatory and reimbursement progress in the U.S. further strengthened our position with key milestones in the fourth quarter. In October, the RemeOs™ Trauma Screw received Transitional Pass-Through Payment status from CMS, underscoring the economic potential of absorbable metal technology. Shortly after, the FDA granted Breakthrough Device Designation for the DrillPin—our third such designation, and a first for any absorbable implant company worldwide. These achievements affirm the clinical and economic relevance and differentiation of Bioretec’s portfolio and highlight our capacity to lead this emerging segment.

### Focus on performance and growth

December marked the announcement of our updated near-term strategy for the period 2026–2028. The strategy prioritizes disciplined execution, capital efficiency, and continued innovation through the expansion of the RemeOs™ platform. Our financial trajectory balances our ambition with the recognition of the resources needed to advance in our key markets and the opportunity for acceleration through key partnerships. The strategy is designed to translate opportunity into results, concentrated resources where we see the strongest clinical demand and commercial return.

Our financial trajectory is both deliberate and balanced. We are advancing priority markets while preserving the flexibility to accelerate through select partnerships that enhance scale, access, or capability. This approach aligns ambition with operating discipline and reflects our commitment to sustainable value creation.

Throughout 2025, Bioretec strengthened its operating foundation. We sharpened

accountability, reinforced the organization, and demonstrated the resilience required to execute through change. The team, fully aligned with the Board and shareholders, has demonstrated the resilience needed to navigate change and has emerged stronger and in position to deliver.

We now enter 2026 with renewed confidence, clear priorities, and a unified organization ready to execute on our priorities. The rebuilding phase was essential; the momentum now begins.

**Sarah van Hellenberg Hubar-Fisher**  
CEO



# Trends driving growth and innovation

## Rising fracture incidence

Aging populations and active seniors result in a rising number of osteoporotic fractures; whilst urbanization, traffic, sports and the prevalence of obesity sustain trauma volumes.

## Surgical standards continue to evolve

Surgical guidelines increasingly favor operative fixation and early mobilization, making absorbable technology a favored solution for an expanding global patient base.

## Growing demand for advanced orthopedic implants

Continued clinical and commercial evidence generation for absorbable materials results in absorbables becoming more mainstream rather than a niche option for patients who demand better outcomes.

## Value-based healthcare

Payers and hospital systems are receptive to premium implants that reduce total cost of care by making removal operations redundant and reducing associated complications and radiological imaging.



# \$14B+ market potential with strong absorbables CAGR

Bioretec operates in the global orthopedic market, estimated at around USD 65 billion in 2025. Bioretec’s strategic emphasis is on orthopedic trauma products, representing roughly 15% of the global orthopedic market. According to market estimates, the global target market for Bioretec’s total product pipeline was valued around USD 14 billion. The United States continues to be the largest market for Bioretec’s products representing two-thirds of the global orthopedic market value and the highest procedure rates and cost per capita.

One of the key areas for Bioretec is the foot and ankle segment, which stands out as a dynamic and growing market and where minimally invasive surgical procedures are becoming a more popular treatment approach for foot and ankle disorders. Bioretec is well positioned to address the growing foot and ankle market segment with its Activa and RemeOs™ product portfolios, whilst capitalizing on expanded segment opportunities in the evolving orthopedic landscape.

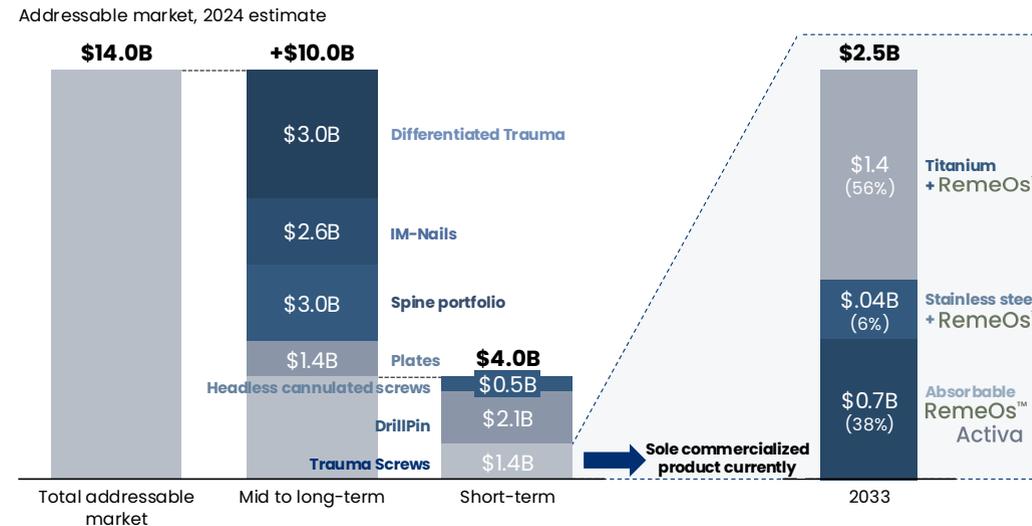
Out of the total orthopedic trauma product market, bioabsorbable orthopedic implants represent a segment with particularly attractive growth potential. This segment of the market is currently estimated at around USD 2 billion, and is growing faster than traditional metal fixation, driven by pressure to reduce operations and align with value-based healthcare. With an estimated CAGR of over 10% between 2026 and 2033, the global bioabsorbable orthopedic implant market is

expected to reach over USD 4 billion by 2033. This growth is driven by global megatrends, such as the ageing of the population and the increase in musculoskeletal injuries. Bioretec is already a recognized market player within this segment.

By 2033, the market for one of Bioretec’s leading product categories, the trauma screw, is expected to reach USD 1.4 billion. The need for high performance absorbable

implants that represent both strength and predictable healing continues to be in demand as reflected by the estimated growth opportunity of the category. Our absorbable portfolio of implants not only demonstrate improved material performance but also aim to enhance both healing and simplify surgical technique of absorbable implants, providing us with the clear opportunity to capture market share globally.

Addressable market for full product line-up >\$14B... ... with strong absorbables outlook (CAGR 10%+)



*Trauma Screw market alone to reach ~\$2.5B by 2033*

**Activa is positioned to capture share in pediatrics, extremities trauma and sports medicine**

**RemeOs™ is positioned to capture share in the complete range of traumatic and orthopedic surgeries**

# Breakthrough technology in absorbable implants

Bioretect combines its unique expertise in materials engineering and chemistry to create safe products based on natural elements. We offer two product families, Activa and RemeOs™, both based on advanced absorbable materials. Backed by extensive clinical evidence, these breakthrough implants offer a healthy solution for bone fracture treatment compared to traditional alternatives. By eliminating the need for removal surgery, our implants offer patients a seamless recovery experience, reduce the risk of complications, and lower the total cost of care.

## Activa

Proven Natural Healing

**ActivaPin™**

**ActivaNail™**

**ActivaScrew™**

**ActivaScrew™ Cannulated**

**ActivaScrew™ Interference**

**Activa IM-Nail™ (pediatric)**

## RemeOs™

Purity and Strength in Healing

**RemeOs™ Screws**

Commercial

**RemeOs™ DrillPins**

**RemeOs™ Staples**

**RemeOs™ Plates**

**RemeOs™ IM-nails**

**RemeOs™ Spinal Cages**

In development

# RemeOs™

Purity and Strength in Healing

**An innovative, bioactive, and absorbable metal alloy that is designed to promote natural bone healing without requiring removal surgery.**

RemeOs™ products are made of magnesium (99%), calcium (>0.55%) and zinc (0.45%). Because RemeOs™ products are composed of physiologically relevant elements essential for bone metabolism, the patient avoids long-term effects caused by the foreign materials in the body.

RemeOs™ combines the fixation strength of traditional metal implants with the unique ability to be osteopromotive and safely absorbed, supporting faster recovery, long-term durability, and sustainability. They carry more load and are well-suited for treating versatile bone fractures. The product is safe and clinically tested, and the material composition promotes bone growth.

The first RemeOs™ product, the trauma screw, is commercially available in both the U.S. and the EU, and in non-European countries where the CE mark is recognized. The RemeOs™ Trauma Screw is the first and only FDA market authorized absorbable metal implant available in the U.S.

Bioretect plans to expand the RemeOs™ product range and indications with several synergistic products in the coming years.

## RemeOs™ product family:

[Read More →](#)

<b>RemeOs™ Trauma Screw</b>	Commercialization phase, FDA market authorization and CE mark, Breakthrough Device Designation
<b>RemeOs™ DrillPins</b>	In clinical trials, Breakthrough Device Designation
<b>RemeOs™ Staples</b>	Development phase
<b>RemeOs™ Plates</b>	Development phase
<b>RemeOs™ IM-nails</b>	Development phase
<b>RemeOs™ Spinal Cages</b>	Development phase, Breakthrough Device Designation

## Key features of RemeOs™:



Controlled absorption over 2–3 years of only natural elements to the body, eliminating need for removal surgery.



Strength retention tailored to match the bone healing.



Easy insertion and safe use. No interference with radiographic imaging<sup>1</sup>.



Osteopromotive and bioactive. Promotes healing and bone growth.

# Activa

## Proven Natural Healing

### Fully absorbable and clinically proven biopolymer products facilitate natural bone healing without requiring removal surgery.

Activa products are based on biopolymer (SR-PLGA) and are ideal for non-load-bearing indications and pediatric patients with proven effectiveness across a broad indication set for orthopedic procedures. Activa implants gradually lose their strength, however, maintaining their function for at least 8 weeks. Complete absorption takes place within approximately two years, thus eliminating the need for implant removal surgery.

Activa implants are specifically designed for stabilizing bone fractures and repairing soft tissue injuries when appropriate immobilization is applied. Backed by more than 20 years of clinical experience, these implants have been used in hundreds of thousands of adult and pediatric procedures with demonstrated safety and effectiveness.

Activa is available across major markets, including the U.S., Europe, and Asia.

### Activa product family:

[Read More →](#)

<b>ActivaPin™</b>	CE mark and FDA 510(k) market clearance
<b>ActivaNail™</b>	CE mark and FDA 510(k) market clearance
<b>Activa Screw™</b>	CE mark and FDA 510(k) market clearance
<b>ActivaScrew Cannulated™</b>	CE mark and FDA 510(k) market clearance
<b>ActivaScrew Interference™</b>	CE mark and FDA 510(k) market clearance
<b>ActivaScrew Interference TCP™</b>	CE mark
<b>Activa IM-Nail™ (Pediatric)</b>	CE mark

### Key features of Activa:



Absorbs safely and gradually into the body within approximately two years, aligning with the natural healing process and eliminating the need for removal surgery.



Ideal for pediatric patients and proven effectiveness in various orthopedic procedures.



Biocompatible - reduces risks of immune response or adverse effects.



Clear intra and postoperative imaging results (X-ray, CT, MRI).

# Research & development in 2025

## The role of research & development

Success in a global, regulated market requires innovation and excellence. Bioretec's team has world-class expertise and a long track record of successful product development and navigating regulatory approval processes. Furthermore, our Scientific Advisory Board of leading medical experts plays a crucial role in guiding our clinical development, training programs and engagement with the surgical community.

We have a strong pipeline for launching additional products. We are especially committed to expanding the RemeOs™ family with several synergistic products in the coming years, with new types of absorbables already in advanced development and clinical trials. R&D remains central to our strategy as we build the next-generation trauma product portfolio designed to eliminate implant removal and to deliver strength, biocompatibility, and predictable healing.

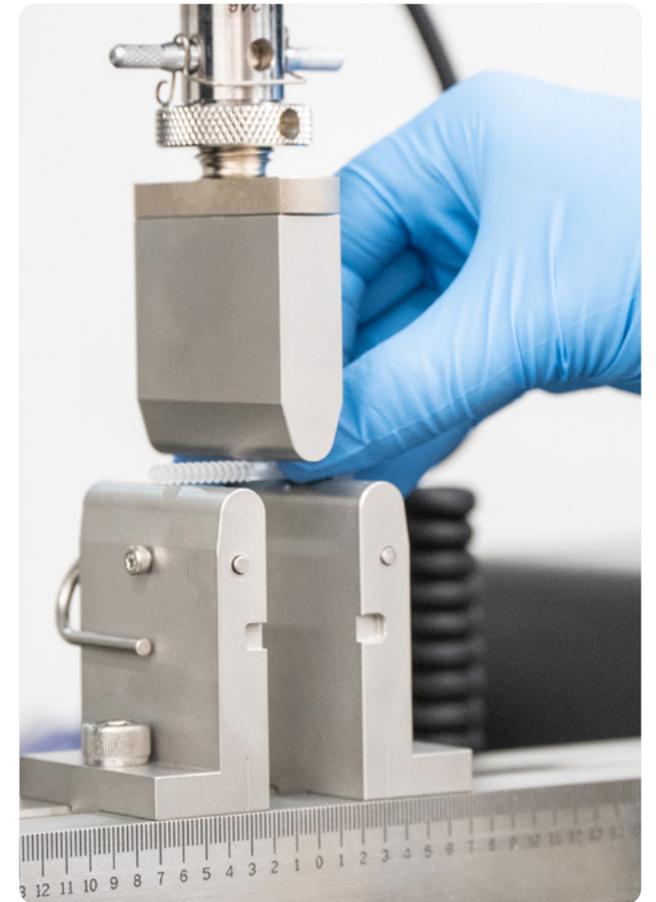
In addition to utilizing the active cooperation with leading medical experts and surgeons, our R&D is conducted primarily in Tampere, Finland. In 2025, our R&D spend was 85.8% of net sales.

## Scientific Advisory Board

Bioretec's Scientific Advisory Board (SAB) works closely with Bioretec's executive team and plays a crucial role in guiding Bioretec's clinical product development, training programs, and engagement with the surgical community. Their expertise and insights are vital in navigating the complexities of introducing the RemeOs™ products to the U.S. and European markets.

In September 2025, Bioretec appointed Dr. Christopher W. DiGiovanni, Professor and Chief of Foot and Ankle Surgery at Massachusetts General Hospital and Harvard Medical School, to its SAB. 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.



# Research & development in 2025

## Product development in the Activa product family

The focus for the Activa product family in 2025 continued to center on product life-cycle management and the updating of existing registrations across a complex and evolving global regulatory landscape. Additionally, the Activa development team concentrated on completing ongoing clinical investigations and on developing the Activa Headless polymer screw, expanding its pediatric, compression and wrist indications.

To facilitate U.S. market entry, Bioretec has developed sterile, single-use instrument kits compatible with its absorbable implant platforms. Development began in January 2025 and was completed by June, with the first ActivaScrew™-compatible kits launched in early July. RemeOs™-specific kits will follow.



## Expanding the RemeOs™ product range and indications

Bioretec is continuing to expand the RemeOs™ product range and indications, with DrillPins, Staples, Plates, IM-Nails and Spinal Cage in the development phase. In addition, a key focus of the R&D activities is the education and training of surgeons to support Trauma Screw sales activities.

In January 2025, Bioretec achieved a major R&D and regulatory milestone with the CE mark approval of the RemeOs™ Trauma Screw product group under the European Medical Device Regulation (MDR). This approval marks the culmination of years of multidisciplinary development, translating advanced materials science into a clinically versatile solution.

The next development phase is focused on expanding the market approvals in the U.S. This is supported by ongoing collaboration

with the FDA and robust clinical evidence from both EU post-market clinical follow-up studies and real-world data. R&D remains central to building the next-generation trauma portfolio, with a focus on eliminating implant removal while maintaining strength, biocompatibility, and predictable healing.

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 product family and absorbable metal alloys as the preferred solution in the absorbable implant market globally. In the medium term, Bioretec also plans to introduce a completely new, differentiated RemeOs™ absorbable trauma product that further showcases the quality and characteristics of the metal alloy solution.

# Continuous New Product Launches, Differentiated Pipeline

## Short term

## Mid term

## Long-Term

**RemeOs™ FT Headless** ~\$0.7B TAM

Fully threaded headless compression screw targeting small bone fixation.



**BREAKTHROUGH DEVICE**

**Differentiated Trauma** ~\$3.0B TAM

ESIN nails, specialty screws, staples, and anchors leveraging absorbable technology.



**Spine Portfolio** ~\$3.0B TAM

SI Joint Screw and Interbody Cages utilizing osteopromotive benefits.



**BREAKTHROUGH DEVICE**

**RemeOs™ DrillPin** ~\$2.1B TAM

Game-changer: Self-drilling pin targeting **850K+ hammertoe surgeries annually.**



**BREAKTHROUGH DEVICE**

**RemeOs™ Upper Extremities** ~\$1.4B TAM

Expansion of indication labels to include wrist, elbow, and shoulder applications.



**IM-Nails** ~\$2.6B TAM

Large bone intramedullary nails for tibia and femur fractures.



**Activa™ Headless** ~\$0.7B TAM

Polymer headless screw expanding pediatric and hand/wrist indications.



**Plates** ~\$4.0B TAM

Comprehensive plating systems replacing permanent hardware.




# Strategic Priorities & Financial Targets for 2026–2028



**Industry leading innovation**

**Demonstrate industry leading innovation**, clinical evidence generation, and **commercial scale** by progressing a strong R&D pipeline and introducing at least **one new product or indication every 12–18 months**, reflected by sustained R&D investments.



**World Class Clinical and Economic Evidence Generation**

Build strong market presence and solidify our commercial position in the U.S. through **direct distribution channels**, targeted Key Opinion Leader engagement strategies, and high-impact training and education.



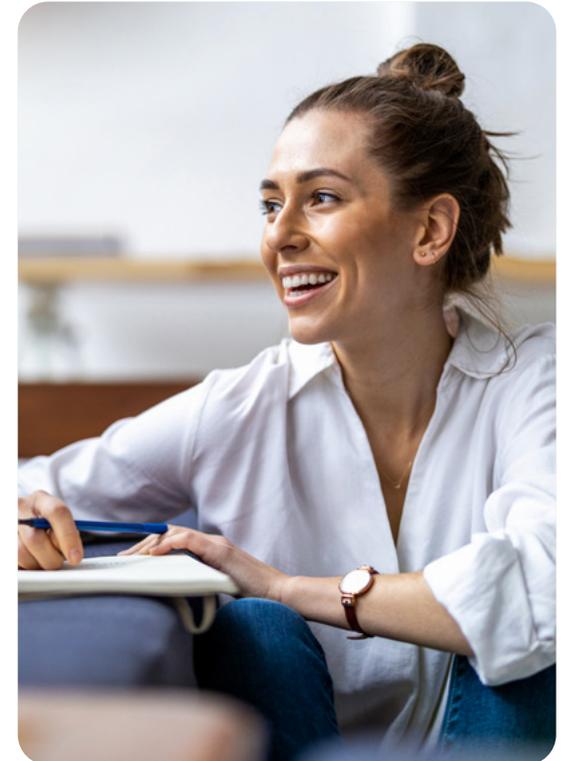
**Global Excellence in Commercialization Generation**

Upgrade our OUS commercial strategy through updated distribution partner selections with rigorous and clear commercial targets and a focused effort on **RemeOs™ launches in high value markets**. Establish RemeOs as the leading **metal alloy absorbable solution** in the orthopedic implant market **globally**.

**Financial Targets**

*Reach **net sales exceeding EUR 10 million** by the end of the year 2028*

*Maintain an **average sales margin exceeding 70%** during the strategy period*



# Commercialization of RemeOs™ in the U.S.

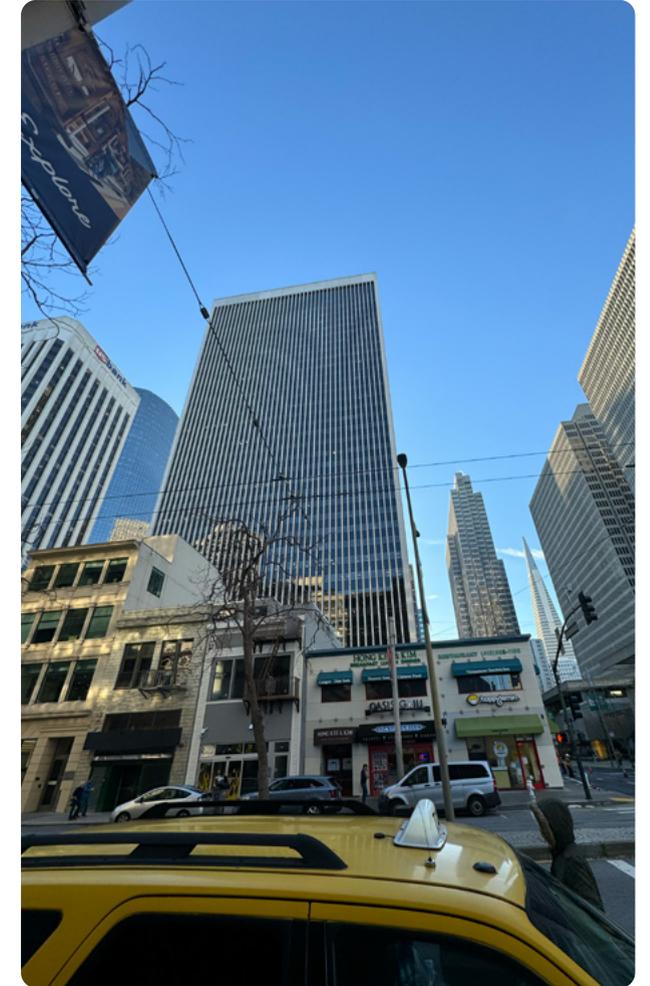
Bioretec’s U.S. commercialization strategy is focused on building out a direct distribution network in key geographies across the country, a clear shift from previous stocking distributor relationships. In 2025 alone, over 20 new distribution parties were contracted by Bioretec to cover major metropolitan areas and other targeted markets the U.S. This direct approach focuses on the foot and ankle segment, leaving room for additional collaboration in upper extremities and continuing our pediatric focused collaboration with Orthopediatrics.

In addition, the expansion of the RemeOs™ product family remains a near term priority for Bioretec and its commercialization strategy. Moving beyond our first De Novo market authorization to expansion of this breakthrough asset pipeline is of key importance to U.S. growth. In the back half of the year, we invested in our Key Opinion Leader program, an additional engagement strategy focused on the development of the U.S. market and supported through training and educational materials and webinars.

Local presence in the U.S. market, anchored in experienced talent, is key to the success of our commercial strategy. In the third quarter of 2025, we invested in strengthening our feet on the ground through the appointment of Blake Helm as VP of Sales, Area West. Blake brings more than twenty years of orthopedic sales distribution management expertise to Bioretec’s growing U.S. presence.

A number of major regulatory milestones to enable our commercialization strategy have already been achieved. In 2021, the U.S. Food and Drug Administration (FDA) granted Breakthrough Device Designation for our RemeOs™ Screw products, confirming that the product represents a clear breakthrough technology in traumatology and orthopedic surgical care. In 2023, the FDA authorized the RemeOs™ Trauma Screw as the first bioresorbable and osteopromotive metal implant in the U.S. market. In addition, the CE mark received in Europe in January 2025 initiated the commercialization process in Europe and other markets with CE mark recognition, and will support the collection

of real-world clinical evidence. This will also enable the expansion of indications in the U.S., where the current product and indication approval is more limited at this time. In October 2025 the RemeOs™ Trauma Screw was granted Transitional Pass-Through Payment (TPT) status by the U.S. Centers for Medicare & Medicaid Services (CMS), recognising the economic benefit of the technology for patient care in addition to the clinical approval. The TPT payment provides hospitals and ambulatory surgical centers with additional reimbursement for new and innovative technologies, lowering the barrier of adoption for the product. Finally, in December 2025, the RemeOs™ DrillPin was granted FDA Breakthrough Device Designation status, solidifying the status of RemeOs™ as now the only absorbable product portfolio with three Breakthrough Device Designations in hand.



# Commercialization of RemeOs™ outside of the U.S. (OUS)

Outside of the U.S., knowing where to focus our time and resources for optimal value is key to our performance. During the end of 2025, we initiated a full review of “where to play” and how to execute by geography in OUS. The upgraded OUS commercial strategy is based on updated distribution partner selections with rigorous and clear commercial targets and a focused effort on RemeOs™ launches in high value markets.

In January 2025, Bioretec received the long-awaited CE mark for the RemeOs™ Trauma Screw product portfolio. The CE mark enables market launch of the RemeOs™ products in Europe and supports commercialization in non-European countries that recognize the CE mark. The comprehensive approval covers all cannulated and non-cannulated product designs, and indications approved include the use of these screws for fracture and malalignment fixations in both the upper and lower extremities of adult and pediatric patients, excluding the hand and forefoot.

The next commercialization steps in Europe are to proceed with country-level approval and registration processes, and to update the relevant sales contracts with existing and new distributors.

In the third quarter of 2025, Jordy Winters was appointed to the role of Vice President of Sales (OUS). With nearly two decades of experience in global orthopedic commercial leadership, Jordy will spearhead Bioretec’s commercialization strategy outside the U.S. and advance our expansion into new markets. 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. In parallel, Rami Ojala, previously VP of Sales (OUS), 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.



# Key investment highlights

**Global pioneer in  
a \$14 billion market**

**Breakthrough technology  
in absorbable implants**

**Future driven by  
a strong R&D pipeline**

**Entering a new era of  
commercialization**



# Bioretec™

Healing Beyond Absorption



**Bioretec Ltd**

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