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Bioretec Ltd Annual Report 2023

FRIDAY 15TH MARCH 2024

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Table of contents

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Bioretec Ltd's Financial Statements 2023 is available at **www.bioretec.com/investors/investors-in-english/reports-and-presentations**

Pioneer in biodegradable orthopedic implants and reformer of surgical treatment

Bioretec is a globally operating Finnish medical device company that continues to pioneer the application of biodegradable* orthopedic implants. The company has unique expertise combining materials engineering and biochemistry in active implants that promote bone growth and facilitate fracture healing after orthopedic surgery. The products developed and manufactured by Bioretec are sold worldwide in approximately 40 countries.

In an era where innovation and total cost of care drives patient care, Bioretec stands at the forefront with the new product line: RemeOs™. In 2023, the RemeOs™ product line achieved a significant milestone with the introduction of the RemeOs™ trauma screw in the U.S. market, following FDA market authorization in March 2023. The deliveries of this product, the first magnesium alloy-based offering from the RemeOs™ line, began in the second half of the year. The EU market authorization for the RemeOs™ screws is anticipated in the second quarter of 2024.

During the year 2023, we expanded the RemeOs™ product pipeline by adding two new product groups to the development, staples and plates, to better serve our customers with more comprehensive product portfolio in addition RemeOs™ Drillpins, IM-nails and Cages. The development of the expanded RemeOs™ product lines focus on using advanced osteopromotive materials, including magnesium alloy and magnesium alloy -based hybrid composites, to improve the strength of biodegradable implants and targeting broader indications and better clinical outcome.

Bioretec's previous generation biodegradable product line, Activa, consists of self-reinforced biodegradable polymer products, is available across major markets, including the U.S., Europe, and Asia. These products are designed for use in various surgical applications, including pediatric, trauma, and sports surgeries.

The RemeOs™ and Activa implants are designed to obviate the need for removal surgery, facilitating the healing process, reducing healthcare costs, and enhancing patient wellbeing. These products not only offer a viable replacement for certain titanium implants but contribute to the advancement of Value-Based Healthcare by improving patient outcomes and operational efficiency.

The majority of Bioretec's revenue is generated from exports, with 99% coming from outside Finland in 2023. Our end customers include both public and private hospitals and hospital chains. Bioretec's products are sold through the company's distribution network.

Bioretec is headquartered in Tampere, Finland, and has subsidiaries in Austria and the United States. The company's share is listed on Nasdaq First North Growth Market Finland. At the end of 2023, the company employed 37 professionals, 36 of whom worked in Finland. In addition, the company's operations are supported by a Scientific Advisory Board consisting of top international surgeons and by a Regulatory Advisor based in the United States.

* In this release the term (bio)degradable is interchangeable with (bio) absorbable and (bio)resorbable

> The RemeOs™ and Activa implants are designed to obviate the need for removal surgery, facilitating the healing process, reducing healthcare costs, and enhancing patient wellbeing.

Bioretec's goal is to improve patients' quality of life and provide significant benefits to patients, the healthcare system and society

Benefits for the patient

- The patient's quality of life improves: patient avoids implant removal surgery and subsequent recovery, as well as the risks of complications typically associated with it, such as nerve damage, inflammation and fracture of the bone after removal.
- The patient avoids hospitalization, sick leave and possible loss of income associated with the implant removal surgery.
- Because the RemeOs™products contain only natural elements essential for bone growth, the patient avoids long-term effects caused by the foreign materials in the body.

Benefits for the healthcare unit

- Biodegradable products allow surgeons to focus on value-added operations rather than on removal surgeries.
- Unlike with traditional titanium and steel implants, magnetic resonance imaging (MRI) is possible after using biodegradable implants.
- The RemeOs™ products do not require surgeons to alter their clinical practice, as their use and surgical methods are consistent with traditional metal implants.

Benefits for society

- The use of the resources in the healthcare system becomes more efficient: the society avoids the costs of removal surgeries caused by treatment and lost productivity.
- Already overwhelmed healtcare system with staffing shortages leading to the unneccessary long waiting times for treatments can be reduced.
- In a country the size of Germany, the implant removal costs have been calculated to be more than EUR 1 billion per year[1].

1) Source: Destatis, Robert Koch Institute, Federal Health Report, refers to year 2014

Year 2023 in numbers

EUR 3.9 M
(EUR 2.9 M)
Net sales

EUR 2.8 M
(EUR 2.1 M)
Sales margin

71.9%
(72.7%)
Sales margin, % of net sales

EUR -2.8 M
(EUR -2.1 M)
EBITDA

37
(28)
Employees at end of year

25.6%
(28.1%)
Share of R&D spend on total costs

8 registered product families (FDA or CE-marked)

~250 implants in portfolio

Products sold in **~40** countries

>35,000 surgical operations in 2023

2023: A landmark year for Bioretec

In 2023, Bioretec achieved a historic milestone by becoming the first player to receive an FDA market authorization in the U.S. for a biodegradable metal product with our RemeOs™ magnesium alloy screw. This landmark achievement not only signifies our entry into the world's largest orthopedic market but also sets a strong foundation for the future commercialization of our innovative RemeOs™ product line. Our continuous efforts in developing advanced, biodegradable orthopedic solutions also resulted in the year ending with the highest net sales in Bioretec's history.

Commercialization of the RemeOs™ trauma screw started in the U.S.

Following the FDA market authorization, we conducted a diligent evaluation process for various distribution channels, which resulted in a partnership with Spartan Medical. This collaboration is particularly strategic, given Spartan's network and experience in both civilian and Department of Defense and Veterans healthcare (DOD & VA) markets. After signing the distribution agreement, we initiated the hospital approvals processes and the roll-out of our RemeOs™ products in chosen top-tier U.S. academic centers and hospitals. As these processes are time-consuming, we are currently awaiting approvals from these selected academic centers and hospitals. The shipments of the RemeOs™ magnesium screws to Spartan started in the fourth quarter of 2023, and the first surgery using the RemeOs™ screws has been performed.

Financial position was strenghtened

Last spring, we took in a significant stride in fortifying our financial position through a successful funding round. Despite the challenges presented by the financial market conditions, we managed to secure EUR 10 million in gross proceeds through a directed share issue targeting institutional and other experienced investors. This capital infusion is vital for our company, as it will catalyze the acceleration of commercialization and distribution efforts for our RemeOs™ product line. Additionally, the funds will be instrumental in furthering our product development initiatives and expanding our production capacity, positioning us well for future growth. Therefore, after the funding round, we marked an anticipated decision in Bioretec's growth trajectory by investing in a new CNC machining center currently dedicated only to our RemeOs™ screws, and the commissioning was completed in January 2024. To further support our growing operations, we've embarked on expanding our production facility space. Additionally, we are investing in a new ERP system scheduled for implementation in 2024. This system is designed to streamline our operations and enhance efficiency, enabling us to surpass our 2023 achievement of delivering products for more than 35 thousand surgical operations. Parallel to these measures, we are also accelerating our product development by expanding our organization and continuing to innovate to meet the evolving demands of the market.

CEO’S REVIEW

> We are preparing the next U.S. market authorization application for the RemeOs™ screws

Strong growth continued

In 2023, we experienced robust growth, with net sales increasing by 33 percent from the previous year, reaching EUR 3.9 million. A significant contributor to this growth was the introduction of our new RemeOs™ screw in the U.S. market, amounting to EUR 374 thousand in its first half year. Meanwhile, China remained a key market for the Activa product group, representing over 50% of our Activa product sales totaling EUR 3.5 million. The sales of RemeOs™ and Activa products in the U.S. showed convincing growth, resulting in nearly 22% of total net sales. In Europe, we faced several market challenges. The discontinuation of deliveries to Russia significantly impacted our operations in Europe. Additionally, this region is still grappling with the aftereffects of the pandemic and acute shortage of hospital staffing, further straining our sales in this market.

CE mark expected in 2024

As we progress into the second quarter of 2024, we anticipate that we will finally obtain the market authorization for our RemeOs™ trauma screw in Europe after expert panel evaluation. The delay is due to prolonged Notified Body approval processes. Obtaining the CE mark will pave the way for the product’s commercialization in the European market. Concurrently, we are set to continue the roll-out of the RemeOs™ screws in the U.S. market and are dedicating substantial resources towards the development of new products in the RemeOs™ series. As part of the expansion plans, we are preparing the next U.S. market authorization application for the RemeOs™ screws, and we have entered into an agreement to conduct a clinical trial of the RemeOs™ DrillPin at the Medical University Hospital in Graz, Austria. This trial is an essential step towards our objective of commercializing the DrillPin in 2025.

Investments in the RemeOs™ product line will continue

As the first half of the year 2024 will partly be burdened by production interruptions (e.g., validation and the ramp-up of our new CNC machining center), we expect our net sales to be generated to a greater extent during the second half of the year. Also, as our RemeOs™ product pipeline is mainly in the development and commercialization phase, we will continue to invest heavily both in S&M and R&D in the forthcoming year. The recruitment process for Bioretec’s new CEO is currently underway, and I am transitioning into another leadership position within the organization. I am thrilled to focus my efforts on the future for supporting the RemeOs™ product pipeline’s forthcoming endeavors. I am confident that together with the new CEO, we will strengthen our growth to transform bone fracture care and significantly enhance patients’ quality of life.

Timo Lehtonen
CEO

Another successful year in the growth trajectory

March: U.S. market authorization for the RemeOs™ trauma screw

We received a De Novo market authorization from the US Food and Drug Administration (FDA) for our biodegradable RemeOs™ trauma screw. This was the world's first U.S. market authorization for biodegradable metal product, which also created a new FDA product classification to the U.S.

April: Updated product range and financial targets as well as share issue

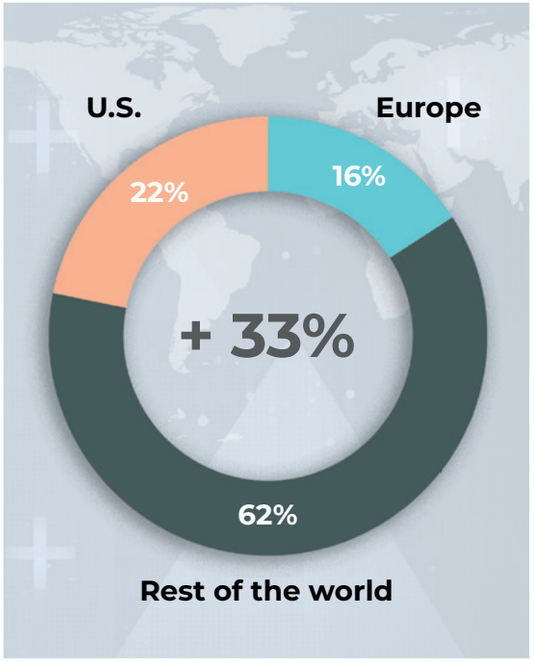
We expanded our product portfolio to better meet demand, refined our market strategy in the United States and updated our financial targets. We also successfully carried out a directed share issue in which we raised EUR 10 million.

September: RemeOs™ trauma screw distribution agreement for the U.S. market

We signed a distribution agreement for the U.S. market with Spartan Medical for RemeOs™ screws. Deliveries to the United States began in the fourth quarter of the year.

Full year: Net sales increased significantly again

Our net sales grew by 33 percent from EUR 2.9 million to EUR 3.9 million. Of the net sales, 16% came from Europe, 22% from the United States and 62% from the rest of the world.



KEY FIGURES

EUR 1,000	2023	2022	Change, %
Net sales	**3,906**	2,942	32.8%
Sales margin	**2,810**	2,139	31.4%
Sales margin, %	**71.9%**	72.7%	
EBITDA	**-2,833**	-2,112	34.1%
EBIT	**-3,034**	-2,292	32.4%
Net profit (loss)	**-3,789**	-2,416	56.8%
R&D spend on total costs, %	**25.6%**	28.1%	
Equity ratio, %	**77.3%**	55.2%	
Cash and cash equivalents	**6,910**	1,223	465.1%
Earnings per share (undiluted)	**-0.19**	-0.17	13.3%
Earnings per share (diluted)	**-0.15**	-0.12	23.4%
Number of shares at the end of the period (undiluted)	**19,536,858**	14,111,858	
Number of shares at the end of the period (diluted)	**24,908,133**	19,608,126	
Personnel at the end of the year	**37**	28	32.1%

SIGNIFICANT EVENTS DURING THE REVIEW PERIOID

● Company release ● Press release

- In March 2023, Bioretec was granted a market authorization according to the De Novo process for its biodegradable RemeOs™ magnesium screw in the U.S.
- In April 2023, Bioretec announced that it will update and refocus its product portfolio and refine its U.S. go-to-market strategy, and consequently update its financial targets.
- In April 2023, Bioretec successfully completed a private placement and raised EUR 10 million.
- In May 2023, Bioretec appointed Dr. Jeremy Dublon as a Regulatory Advisor to support the company's U.S. go-to-market strategy.
- In June 2023, Bioretec invested in a CNC machining center to increase the RemeOs™ production capacity.
- In August 2023, Bioretec announced its revised Scientific Advisory Board, whose members are the world's leading orthopedic experts in their own specialty.
- In September 2023, Bioretec entered into an agreement with Spartan Medical for the RemeOs™ screws launch in the U.S.
- In October 2023, Bioretec changed its estimate for the granting of the European market authorization for its biodegradable RemeOs™ trauma screw and estimated that the approval will move to the first quarter of 2024. After the reporting period, the company updated its estimate and transferred the expected timing of receiving the market authorization to the second quarter of 2024.
- In November 2023, Bioretec´s Board of Directors initiated a recruitment process for a new CEO.

RemeOs™ controlled launch ongoing

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Former FDA medical officer joined Bioretec as a regulatory advisor to support RemeOs™ market entry to U.S.

Bioretec's introduction of the RemeOs™ magnesium alloy screw in the U.S. market represents a significant milestone for the company, marking the first instance of FDA market authorization for a biodegradable metal product in the United States. This achievement shows Bioretec's leadership in innovative biodegradable implant technology and sets the stage for the next commercialization phases in the U.S.

Strategic focus areas of commercialization

The launch strategy for the RemeOs™ trauma screws is designed to ensure a controlled market introduction with a phased approach, emphasizing collaboration with local Key Opinion Leaders (KOLs), well-known academic centers, and clinical professionals focusing on ankle fractures. This chosen controlled roll-out aims to build confidence in the innovative breakthrough technology among U.S. clinics, with sales expected to gradually increase as the market familiarizes itself with the product's benefits. This gradual approach is supported by collecting real-world clinical evidence for Post-Market Surveillance (PMS), marketing, and the creation of additional value dossiers for private insurance companies.

For U.S. distribution, Bioretec partnered with Spartan Medical in September 2023. This collaboration is essential given Spartan's shared view on launching products in civilian healthcare and its recognized status within the Department of Defense and Veterans' Health Care (DoD and VA) markets. The partnership commenced on deliveries of the RemeOs™ magnesium alloy trauma screws to Spartan Medical in the fourth quarter of 2023, and the first surgeries using the RemeOs™ screws have been completed.

CONTROLLED LAUNCH STRATEGY WITH SPARTAN MEDICAL

1. **Strategic control: Bioretec maintains oversight of product positioning and market targeting, ensuring a focused introduction in the initial phase. The launch strategy differentiates between the civilian segment, targeting a selected number of academic and trauma centers, and the DoD/VA segment, utilizing Spartan's established networks.**
2. **Data access: The strategy provides Bioretec with valuable insights into customer usage patterns, surgeon community feedback, and patient experience, facilitating informed decision-making and strategy refinement.**
3. **Expertise in the new market development: Bioretec has engaged product specialists, known for their market development expertise, lead distributor training and support marketing activities, ensuring that healthcare professionals receive comprehensive education on the product's benefits.**
4. **Education and training: Bioretec designs and implements the education and training program to ensure that surgeons and healthcare professionals have a comprehensive understanding of the product's benefits.**

The RemeOs™ biodegradable metal is composed of natural elements found in the human body **Magnesium (Mg), Calcium (Ca) and Zinc (Zn)**

Mg alloy with Ca 0.55 w-% and Zn 0.45 w-%

Excellent biocompatibility
= safe

Bioactive, osteopromotive properties
= enhanced bone growth

Rapid bone ingrowth, regeneration, and replacement
= makes removal operations redundant

Strength retention tailored to match the bone healing
= carries the load over the healing period

Fixation strength comparable with conventional metal implants
= no screw loosening due to gas evolution

Easy insertion and use, comparable to conventional metal implants
= common surgigal techniques

REMEOS™ IN THE U.S. MARKET

Following the distribution agreement, Bioretec initiated the hospital approval processes, targeting to leading academic centers and hospitals for the launch of RemeOs™ trauma screws. Typically, the sales process to access Ambulatory Surgery Centers (ASC) and small private hospitals takes around 3-6 months and larger Integrated Delivery Networks (IDNs) 6-10 months.

Strategic steps for achieving hospital approvals

The strategy for gaining hospital approval also involves a multi-faceted approach. This sales strategy includes engaging U.S. Key Opinion Leaders, demonstrating product performance through workshops or cadaver training, and highlighting the RemeOs™ products' value proposition with measurable performance metrics. It also involves understanding strategic decision-making points, such as procedure volumes and reimbursement aspects, and engaging users through the entire product cycle.

Given the time-intensive nature of these approvals, Bioretec is currently at different stages in navigating the approval processes in selected centers.

> Typically, the sales process to access Ambulatory Surgery Centers (ASC) and small private hospitals takes around 3-6 months and larger Integrated Delivery Networks (IDNs) 6-10 months.

The role of the Scientific Advisory Board

Bioretec's Scientific Advisory Board (SAB) 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. market.

This strategic, phased approach to commercialization emphasizes Bioretec's commitment to introducing sustainable, innovative solutions to the U.S. healthcare market. By focusing on collaboration with key stakeholders, controlled market entry, and thorough engagement with the medical community, Bioretec aims to establish the RemeOs™ magnesium alloy screw as a trusted option for clinicians and patients alike.

SCIENTIFIC ADVISORY BOARD

Leading experts supporting throughout the lifecycle of products

SAB 2023 ANNUAL MEETING AND WORKSHOP AT TURKU, FINLAND 14-16.9. 2024

A key component of Bioretec's development strategy is the invaluable guidance and support of leading experts in the field. The role of Bioretec's Scientific Advisory Board (SAB) is to support Bioretec's operations throughout the life cycle of products, from early-stage concepts through product development to commercialization and continuous product support. The SAB acts as a channel to key opinion leaders, experienced surgeons who act as trendsetters in the introduction of new technologies in their areas of expertise. In addition to specific topic meetings with certain members of the team, Bioretec has regular quarterly and annual meetings with the entire SAB.

Trauma advisors

Prof. Dr. Klaus Dresing, Germany

Chairman of the SAB since 2021
Chairman of the AO Alumni Association, member of the AO Trauma International Board

Prof. Dr. Fan Liu, China

Member of the SAB since 2021
Vice President, Chief and Professor in Department of Orthopedic Surgery, Affiliated Hospital to Nantong University

Pediatric advisors

Prof. Dr. Theddy Slongo, Switzerland

Member of the SAB since 2023
Head of Pediatric Surgery and Child Traumatology, Children's Clinic, Bern

Dr. Verena Schreiber, USA

Member of the SAB since 2023
Pediatric Orthopaedic Surgeon, Nicklaus Children's Hospital Orthopedic, Sports Health, and Spine Institute in Miami

Spine advisors

Prof. Dr. Jeffrey Wang, USA

Member of the SAB since 2023
Professor of Orthopaedic Surgery and Neurosurgery, the Keck School of Medicine at the University of Southern California (USC)

Prof. Dr. Richard Assaker, France

Member of the SAB since 2023
Professor in Neurosurgery, Hopital Roger Salengro, Lille

Ankle and foot advisors

Prof. Dr. Stefan Rammelt, Germany

Member of the SAB since 2023
Professor of Trauma & Reconstructive Surgery, Head, Foot & Ankle Center, University Hospital, Dresden

Dr. Robert Leland, USA

Member of the SAB since 2023
Clinical Assistant Professor in the Department of Orthopedics at the University of Colorado

Next steps driving the RemeOs™ development

In 2023, Bioretec reached a historic milestone when the RemeOs™ trauma screw was the first biodegradable metal implant in the world to receive a market authorization from the FDA for the U.S. market, which is also a significant leap forward in the company's development work. Following this achievement, Bioretec has focused its research and development efforts on expanding the RemeOs™ product range and indications.

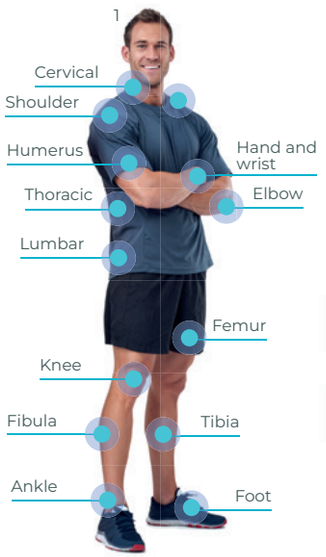
New RemeOs™ product family

Bioretec secured the market authorization in the U.S. for its RemeOs™ trauma screw in March 2023. Manufactured from a proprietary biodegradable metal composed of magnesium, calcium, and zinc, the RemeOs™ implants represent a breakthrough in orthopedic technology. Following the granted market authorization, Bioretec updated the RemeOs™ product pipeline with two new product groups, staples and plates. These additions are designed to complement the existing RemeOs™ trauma screw and DrillPin product groups and to serve surgeons with a more comprehensive and synergistic offering. RemeOs™ staples find their primary indications in the foot and ankle area, serving to stabilize fractures or osteotomies, and promoting rapid bone healing either independently or in conjunction with the RemeOs™ trauma screws. RemeOs™ plates provide additional support for similar indications, especially in cases of multiple fractures in the same anatomical location.

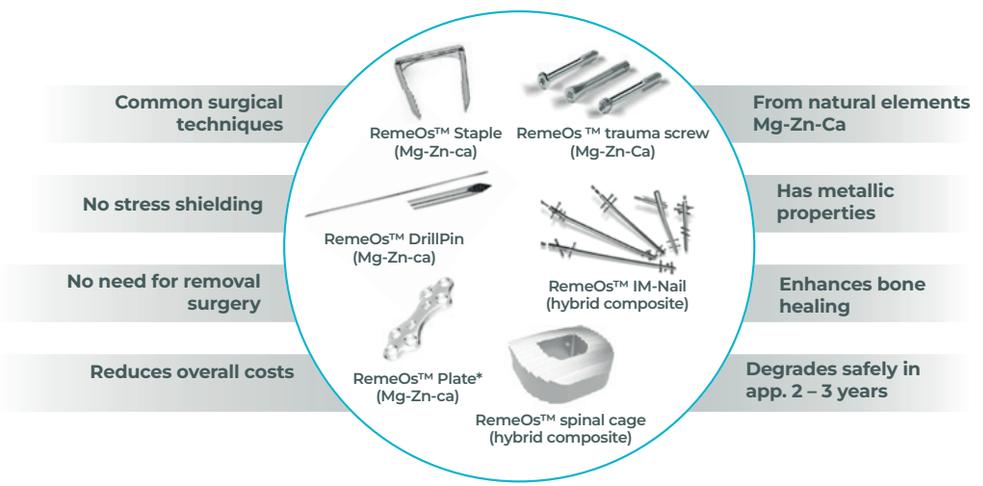
The anticipated and pending CE Mark authorization of the RemeOs™ screws for the European market, expected in the second quarter of 2024, has not slowed Bioretec's momentum in R&D. The company has continued advancing in the development of the RemeOs™ screw product group and its indications for the U.S. market. In the fall of 2023, Bioretec's interactive Sprint discussions with the FDA, conducted under the Breakthrough Device Designation program, have been instrumental in paving the way for the next steps for RemeOs™ screws. Looking forward, the company is preparing to submit its next market clearance application leveraging the more streamlined 510(k) regulatory pathway, during 2024.

Furthermore, the development of the RemeOs™ DrillPin product group has reached the next phase. During the last quarter of 2023, Bioretec finalized an agreement to conduct a clinical trial at the Medical University Hospital in Graz, Austria, and started an ethical committee approval process. The purpose of this trial is to validate the safety and effectiveness of the RemeOs™ DrillPin. The RemeOs™ DrillPin product group is positioned to serve both adult and pediatric patients, addressing a broad spectrum of orthopedic indications.

In addition to the RemeOs™ screws and DrillPins, Bioretec is continuously progressing in the development of other RemeOs™ products in the pipeline. These cutting-edge products are currently undergoing product development, applicability assessment, and research, paving the way for even more transformative solutions in the future. With the expanded product portfolio, Bioretec has updated the commercialization timeline for the RemeOs™ DrillPin, now expected in 2025, adjusted from the original forecast of 2024.



RemeOs™ product pipeline



Manufactured from RemeOs™ alloy[2] and patented hybrid composite[3]

[1]) Final indications and anatomical locations of RemeOs™ products in each market depend on regulatory approvals in connection with each product's market authorization.

[2]) Magnesium alloy based on all-natural elements. No Rare Earth Elements (REE).

[3]) Hybrid composite is based on RemeOs™ magnesium alloy containing one biodegrabable polymer matrix combined with two different biodegrabable reinforcements.

RESEARCH AND DEVELOPMENT

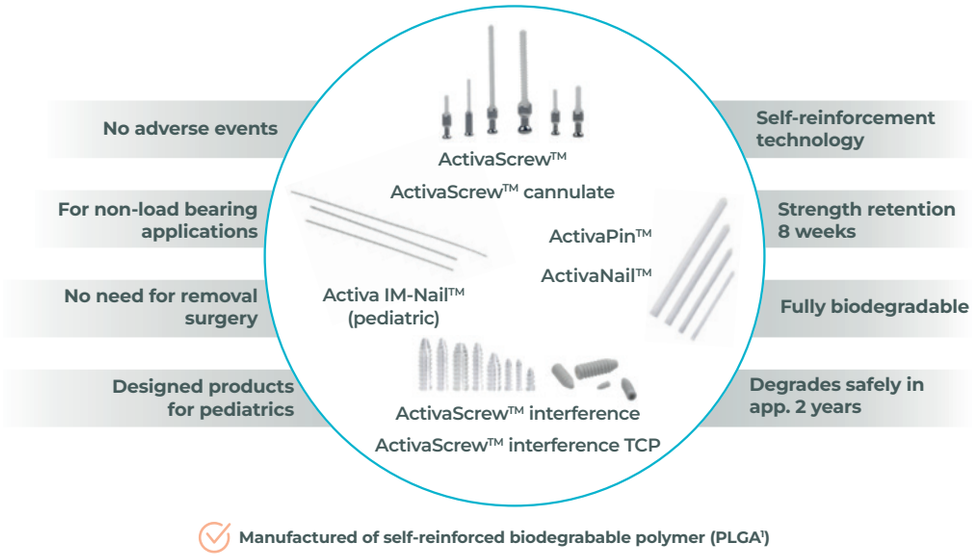
Bioretec anticipates the launch of RemeOs™ staples in 2026 and RemeOs™ plates in 2027. Furthermore, the introduction of the IM-Nail and the spinal cage, previously estimated for 2026 and 2027, is now anticipated post-2028. Moreover, an ongoing study evaluating different coatings for enhancing future product properties, supported in part by Business Finland, commenced in autumn 2023, highlighting Bioretec's commitment to R&D.

Current Activa product family

Bioretec is also continuing development of the properties and application areas of its current commercially available Activa implants. Activa implants are biodegrabable implants made of PLGA (poly-lactide-co-glycolide copolymer), with a long history of medical use.

The Post-Market Clinical Follow-up (PMCF) multicenter study on the biodegradable Activa IM-Nail™ for pediatric forearm fractures is progressing across Europe, aiming to assess refracture rates and subjective benefits of Activa IM-Nail™ for patients, parents, and caregivers. By the end of 2023, 81% of the target group was treated, nearing patient enrolment completion. Additionally, another ongoing clinical trial investigates Activa IM-Nail™ for the treatment of pediatric wrist fractures (Distal Radius) and is conducted as a comparative trial alongside permanent metallic K-wires. The patient enrolment is completed, and reporting is ongoing. Bioretec expects the results to be published in the forthcoming joint Congress of European and North American Pediatric Societies (EPOSNA) in May 2024.

Current Activa products



¹) The poly L-lactide-co-glycolide copolymer has a long history in medical use, and the monomers, building blocks of PLGA, are part of the normal chemistry in cells.

The Post-Market Clinical Follow-up (PMCF) multicenter study on the biodegradable Activa IM-Nail™ for pediatric forearm fractures is progressing across Europe.

Large and steadily growing market

> Small innovative companies lead the development.

Bioretec operates in the global orthopedic market, which grew well above historical rates to an estimated USD 59.1 billion in 2023, up from USD 55.5 billion in 2022. The growth of 6.5% was due to the resumption of surgeries postponed during the pandemic. In 2023, the overall market was about three basis points higher than its historical growth rate, and the growth is expected to continue modestly through 2024.

Bioretec's strategic emphasis is on orthopedic trauma products, and which was valued at approximately USD 8.6 billion in 2023. In 2023, the largest geographic market in orthopedic trauma products was the United States, with a 66% share. The U.S. is currently the main target market for Bioretec.

One of the targets within the orthopedic trauma market for Bioretec is the growing foot and ankle segment. Given the segment's vast array of treatments and products, it forms a key focus area in Bioretec's short and medium-term product pipeline. Industry forecasts project a robust 7% annual growth rate for the market from 2021 to 2025, potentially reaching a total market value of USD 5.6 billion in 2025. Bioretec is well-positioned to leverage this potential and capitalize on the opportunities in the evolving orthopedic landscape.

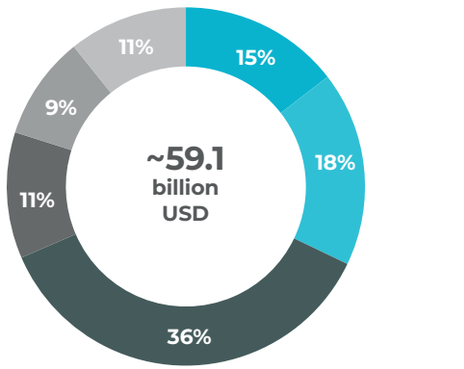
In the long term, the orthopedic trauma market is poised for continued growth, driven by demographic shifts toward an aging population and rising instances of diabetes and obesity. Bioretec is committed to innovating and providing valuable solutions in orthopedic treatment by improving the quality of patient lives and making an impact in global healthcare.

Small companies as innovators

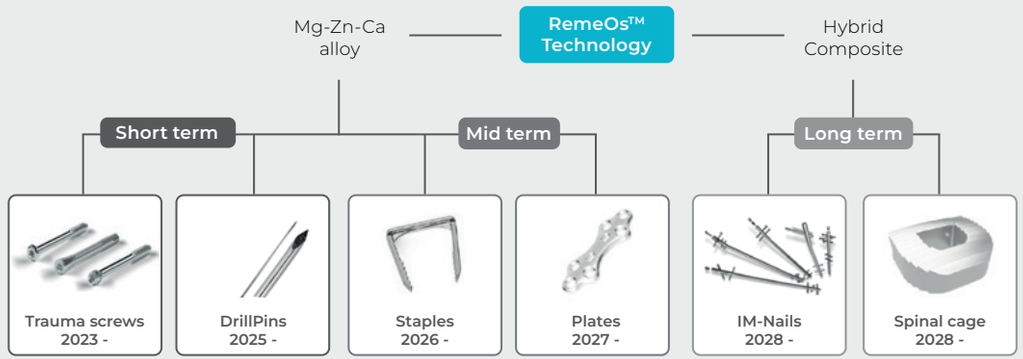
While there are hundreds of companies operating in the market for orthopedic products, the market is mainly concentrated in a small number of large companies. In 2024, it is estimated that more than 60% of all orthopedic sales are generated by just six major companies, each with over USD 2 billion in annual sales. In trauma products, the biggest players on the market are largely the same companies.[1]

Despite the concentration of the market, small companies play an important role in creating innovation in the industry. Large manufacturers of orthopedic products are not developing biodegradable orthopedic metal implants, and besides Bioretec, there is a very limited number of companies that develop, manufacture and market them.

Global orthopedics market 2023

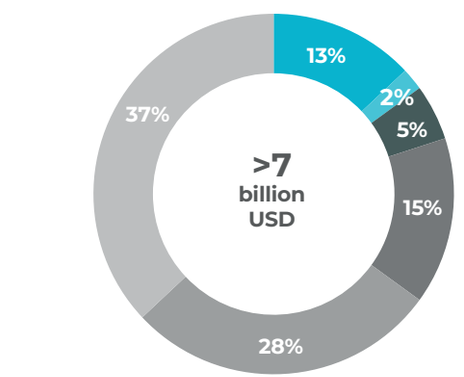


RemeOS™ Product Group Pipeline



Estimation of commercialization of each group's first products. Possible anatomical locations and final indication of RemeOs™ products depend on regulatory approval in connection with each product's marketing authorization

Total addressable market for Bioretec's products



[1]) Source for market forecasts: Orthoworld: The Orthopaedic Industry Annual Report 2022 ja Orthopedic Market 2022 Projections & 2023 Outlook.

Market trends

THE SHARE OF THE ELDERLY POPULATION IS INCREASING

Older people have a higher risk of bone fractures, so the increase in the proportion of elderly population supports the growth of Bioretec's addressable market.

THE NUMBER OF TRAUMA IS INCREASING

The number of fractures is expected to increase with, for example, the increasing popularity of diverse extreme sports and prevalence of obesity.

GROWING DEMAND FOR ADVANCED ORTHOPEDIC IMPLANTS

Patients are increasingly aware of different treatment methods, which supports the demand for biodegradable orthopedic implants.

LACK OF OPERATION ROOM AND HEALTHCARE PROFESSIONAL CAPACITY

With biodegrabable implants, no removal operation is required. This provides extra healthcare capacity and reduces operating room queues.

VALUE BASED HEALTHCARE

In the value-based healthcare model, hospitals and physicians are paid based on patient health outcomes, focusing on the quality rather than the quantity of services provided.

Our strategy focuses on the commercialization and development of new RemeOs™ products

Vision	**Bioretec's vision is to become a globally recognized medical device company and a leader in biodegradable metal implants.**
Mission	**Bioretec's mission is to introduce novel, innovative, high-quality biodegradable surgical solutions that enable better healing, safety and cost-efficiency in clinical care.**
Goal	**Bioretec's goal is to improve people's quality of life globally, with an innovation that can heal bone fractures and deformities more durably and with fewer surgeries**

Bioretec's strategy

- **Development and commercialization of the RemeOs™ products**
- **Maintaining world-class talent and capabilities in the organization**
- **Achieving high profitability**

Financial targets

Bioretec updated its financial targets in April 2023. Previous financial targets were EUR 100 million net sales by the end of 2027 and positive operative cash flow by the end of 2025

Net sales EUR 62 million

in a global over USD 7 billion total addressable market by the end of 2027

Positive cash flow from operating activities

by the end of 2026

BIORETEC AS AN INVESTMENT

1. **Attractive market** – global total addressable market of ~USD 7 billion with increasing demand for orthopaedic implants

2. **Superior solution for patient healing** – magnesium-based biodegradable implants promote bone healing and eliminate need for implant removal

3. **The first biodegradable* metal product group authorized in the US**

4. **Strong pipeline for launching additional products in coming years**
– the market authorization paves the way for next products

5. **Experienced management team executing commercialisation plan**
– supported by top-quality SAB

*In this release the term (bio)degradable is interchangeable with (bio)absorbable and (bio)resorbable

Information for shareholders

More information for investors at **www.bioretec.com/investors/investors-in-english**

Bioretec Ltd's share is listed on the First North Growth Market Finland marketplace maintained by Nasdaq Helsinki under the trading code BRETEC. Bioretec has one class of shares. Each share confers equal voting rights and the shares in the company confer equal rights to dividends. There are no voting restrictions on the shares.

Dividend policy

The company's business has been unprofitable so far. Due to this, it has not distributed any dividends. In the near future, the company will focus on financing its growth strategy and development of its business. The company does not expect to distribute dividends in the short or medium term. In the long term, the company's dividends and their distribution are linked to the company's results of operations and financial position.

Distribution of profit

The Board of Directors of the company proposes that the parent company loss of EUR 3,721,314.67 for the financial period from 1 January to 31 December 2023 be credited in the equity as Profit(loss) for previous accounting periods and that no dividend be distributed.

Financial reporting in 2024

In 2024, Bioretec will publish the following financial reports:

- business review for January–March 2024 on Thursday 16 May 2024
- half-year report for January–June 2024 on Thursday 15 August 2024
- business review for January–September 2024 on Thursday 14 November 2024

Financial reports will be available on the company's website, once they are published, at www.bioretec.com/investors. The company's releases can be subscribed using the form available on the website. Bioretec maintains a 30-day silent period in its investor and media contacts prior to the publication of its financial statements bulletins and half-year reports.

Annual General Meeting

Bioretec's Annual General Meeting is planned to be held on Friday, 26 April 2024. Bioretec's Board of Directors will convene the Annual General Meeting separately at a later date.

Bioretec's Inverstor Relations

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INFORMATION FOR SHAREHOLDERS

EUR 2.53
Average price in 2023
(EUR 2.31 in 2022)

EUR 2.4
Closing price on
29 December 2023
(EUR 1.41 in 2022)

EUR 46.9 million
Market capitalization on
29 December 2023
(EUR 19.8 million
in 2022)

10 largest shareholders on 31 December 2023

	Shareholder	Shares	% of shares
1.	Stephen Industries Inc Oy	1,600,000	8.19%
2.	Ilmarinen Mutual Pension Insurance Company	1,350,000	6.91%
3.	Innovestor Kasvurahasto I Ky	949,945	4.86%
4.	University of Helsinki Funds	917,966	4.70%
5.	Danske Invest Finnish Equity Fund	703,094	3.60%
6.	Eakr-Aloitusrahasto Oy	606,370	3.10%
7.	Säästöpankki Small Cap Mutual Fund	545,000	2.79%
8.	VR Eläkesäätiö	473,8122	2.43%
9.	Orion Pension Foundation	464,622	2.38%
10.	OP-Finland Small Firms Fund	445,000	2.28%
	10 largest shareholders in total*	**8,055,809**	**41.24%**
	Other	**11,481,049**	**58.76%**
	Total	**19,536,858**	**100.00%**

*) The list of 10 largest shareholders does not include nominee-registered owners.

Share price development 2 January–29 December 2023

Marketplace: Nasdaq First North Growth Market Finland
Trading code: BRETEC
ISIN code: FI4000480454

Management Team on 31 December 2023

Timo Lehtonen

CEO since 2019

Johanna Salko

CFO since 2021

Kimmo Lähteenkorva

CTO since 2017

More detailed CV information:
https://bioretec.com/investors/investors-in-english/governance/management-team

Esa Hallinen

Director of Operations
since 2023

Rami Ojala

Sales and Marketing Director
since 2022

Mari Ruotsalainen

Director, QA & RA
since 2018

Minna Ahlstedt-Soini

Production Director
since 2015

Board of Directors on 31 December 2023

Tomi Numminen

Chairman of the Board of Directors since 2019, Member of the Board since 2016*

Professional board member

Michael Piccirillo

Member of the Board since 2018**

Managing Director, VALUGEN GmbH

Pekka Simula

Member of the Board since 2020**

Partner, Innovestor

Sarah van Hellenberg Hubar-Fisher

Member of the Board since 2021*

Healtcare industry professional, board member and venture leader

Päivi Malinen

Member of the Board since 2022*

Laissa Oy, business partner

Kustaa Poutiainen

Member of the Board since 2023**

President and Chairman of the Board, Stephen Industries Inc Oy

More detailed CV information:
https://bioretec.com/investors/investors-in-english/governance/board-of-directors

*Audit committee
**Remuneration and nomimination committee

bioretec

better healing – better life

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www.bioretec.com