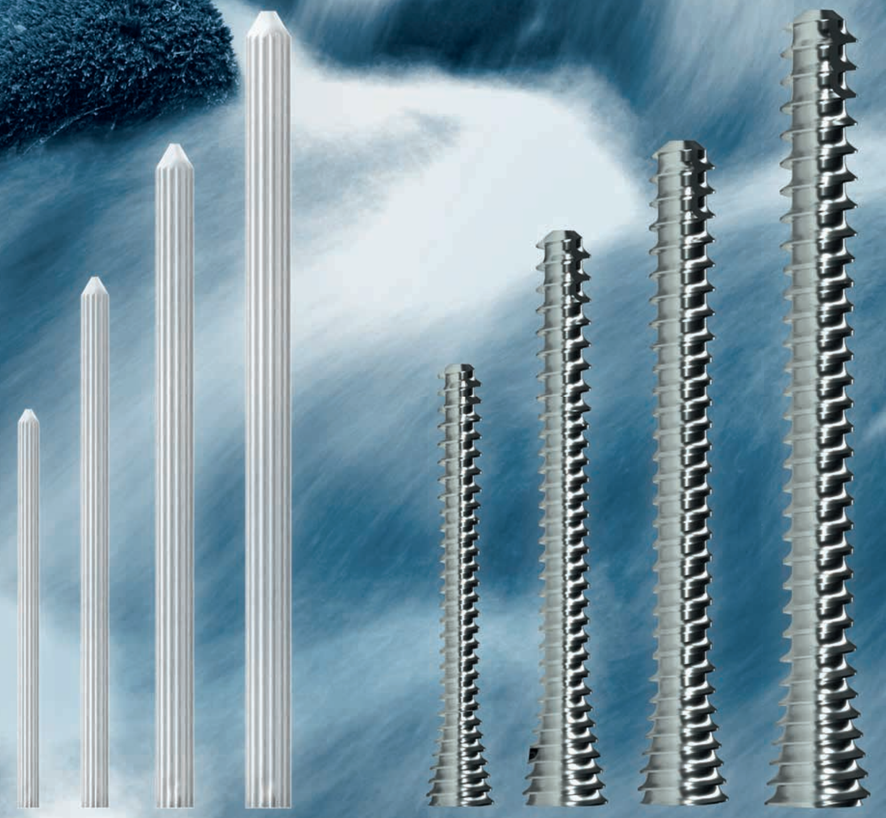
bioretec

Better healing – Better life.

Bioretec Ltd Annual Report 2024



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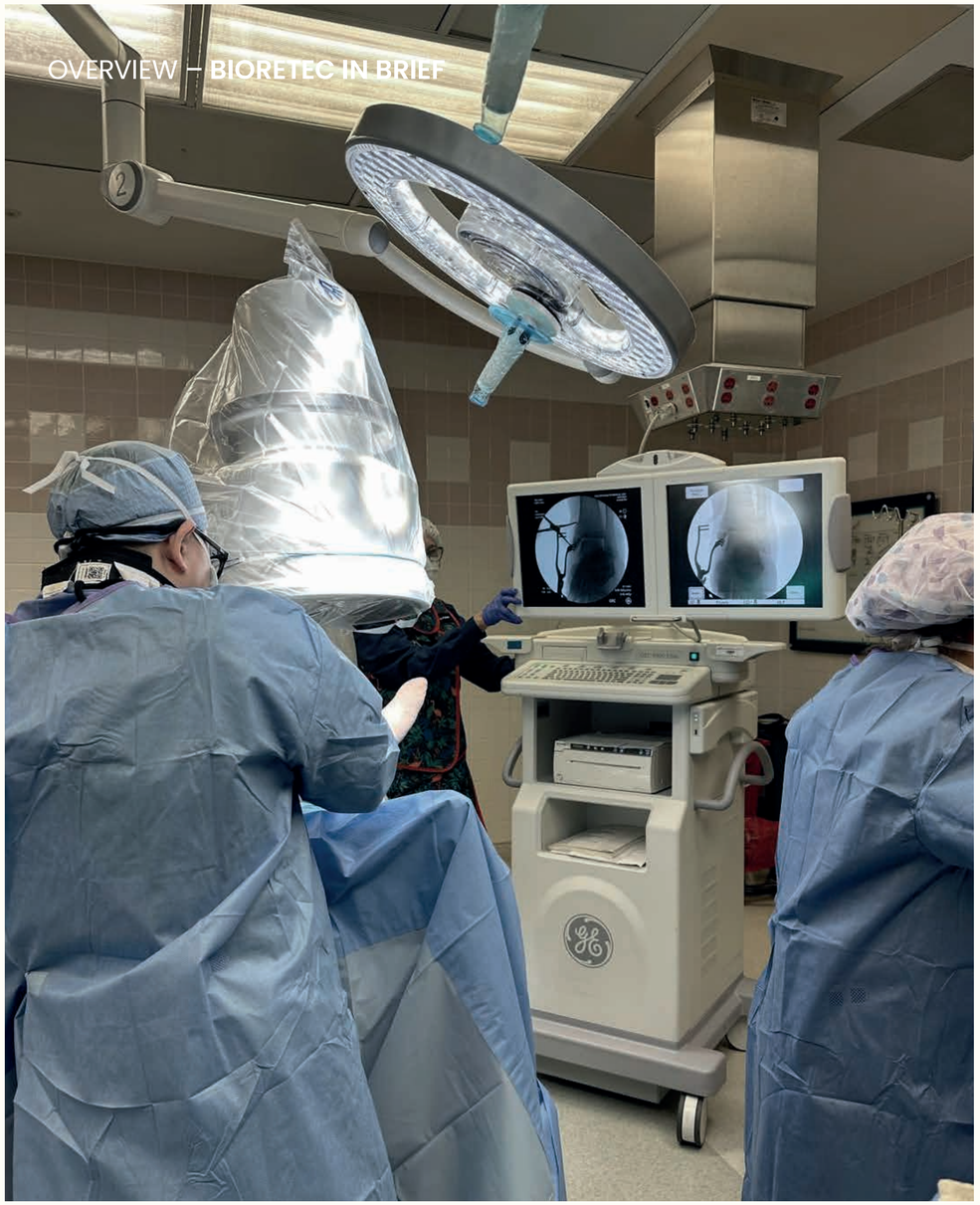
BUSINESS OPERATIONS

Bioretec Ltd. is a medical device company focusing on the sales and development of strong, safe and reliable absorbable implants for pediatric and adult orthopedics. Our products are used worldwide, and we continue to further develop solutions to shorten the overall recovery times and enhance the quality of patient care.

Read the financial statement 2024 on bioretec.com

Overview



Bioretec in brief

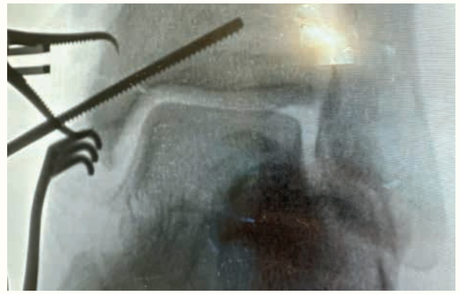
Pioneer in absorbable orthopedic implants and reformer of surgical treatment

Bioretec is a globally operating Finnish medical device company that continues to pioneer the application of absorbable 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 sales of the first magnesium alloy-based product of the RemeOs line started in the second half of 2023.

In 2024, the launch of RemeOs Trauma Screws in the U.S. yielded excellent patient results, with a notable number of surgeries and successful post-healing follow-ups. This success lays the groundwork for driving strong demand within the surgeon community and launched the second phase of commercialization for RemeOs products in the U.S. in late 2024.

In January 2025, Bioretec received the long-waited CE mark for the RemeOs Trauma Screw product portfolio. The CE mark enables immediate market launch of the RemeOs



products in Europe and supports commercialization in non-European countries that recognize the CE mark. This 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.

Bioretec's previous generation absorbable product line, Activa, consists of self-reinforced absorbable polymer, 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.

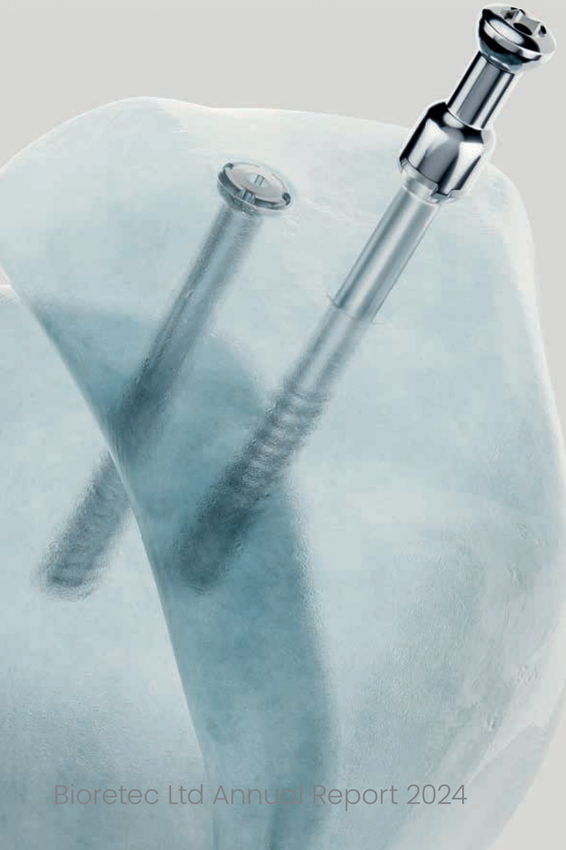
The RemeOs™ and Activa implants are designed to obviate the need for removal surgery, facilitating the healing process, reducing healthcare costs, and enhancing patient wellbeing. These products not only offer a viable replacement for certain titanium implants but contribute to the advancement of Value-Based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

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

Most of Bioretec's revenue comes from outside Finland. In 2024, exports accounted for 99% of revenue. Our end customers include both public and private hospitals and hospital chains. Bioretec's products are mostly sold through the company's distribution network. In certain markets, products are also sold directly to customers.

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 2024, the company employed 47 professionals, of whom 44 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.

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 significantly improves as they avoid the need for implant removal surgery and the associated recovery period. Additionally, our implants eliminate the risks of complications commonly linked to such procedures, including nerve damage, inflammation, and bone fracture following implant 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
Healthcare

Absorbable products allow surgeons to focus on value-added primary operations rather than on removal surgeries enhancing efficiency in healthcare units.

The RemeOs products do not require surgeons to alter their Operation room practices, as their use and surgical methods are consistent with traditional metal implants.

Unlike with traditional titanium and steel implants, magnetic resonance imaging (MRI) is possible after using absorbable 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 healthcare system with staffing shortages leading to the unnecessary 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 2024 in numbers

4.5
MEUR
Net sales
(EUR 3.9 million)

3.4
MEUR
Sales margin
(EUR 2.8 million)

74.6
Sales margin, % of net sales
(71.9 %)

-4.0
MEUR
EBITDA
(EUR -2.8 million)

47
Employees at end of year
(37)

28.7
Share of R&D spend on total costs, %
(25.6 %)

8
Registered product families
(FDA or CE-marked)

~250
Implants in portfolio*

~40
Countries where products are sold

>42
Thousand surgical operations in 2024

* Bioretec received CE-mark registration for its RemeOs™ Trauma Screw products in January 2025. These new products are not yet included in the total number of implants.

Year 2024 in highlights

Major advances in market approval processes, product development and IPR

March

FDA Breakthrough Device Designation status and a patent by the U.S. Patent Office

We were granted an FDA (the U.S. Food and Drug Administration) Breakthrough Device Designation status for our RemeOs Spinal Interbody Cage as well as a core patent by the U.S. Patent Office for RemeOs absorbable magnesium alloy composition.

May

Alan Donze as Bioretec's new CEO

We announced the appointment of Alan Donze as our new Chief Executive Officer. With a distinguished career spanning the banking and medical device industries, Alan Donze brings a wealth of experience and expertise to our organization.

June

Positive clinical outcomes in the U.S. and an update from CE mark process

Following the launch of the RemeOs Trauma Screw, we reported favorable clinical outcomes, with fracture healing confirmed in 100% of surgical procedures. Additionally, following expert panel review, the CE mark authorization was expected later than the earlier estimate (Q2/2024).

October

Updated product development strategy and financial targets

We updated our product development strategy and announced we will accelerate the product development of the RemeOs Spinal Interbody Cage. Furthermore, our Board of Directors updated the financial targets.

November

New logistics and distribution channels established for the U.S. market

To enhance market penetration of the RemeOs and Activa products in the U.S., we entered into two new agreements. We signed a new logistics agreement for U.S. operations with customer support services provider GlobalMed Logistix and a new sales and distribution agreement with Tri-State Biologics.

November

Oversubscribed private placement

We arranged a private placement for institutional and other experienced investors. Through a significantly oversubscribed private placement, we raised gross proceeds totaling EUR 6.0 million, which will be used to strengthen the commercialization of the RemeOs products and to accelerate the product development of the RemeOs Spinal Interbody Cage.

Our persistence pays off - CE mark received in January 2025

For Bioretec, year 2024 was a great achievement as we managed to grow our net sales despite the delayed market approvals and significant investment in building out our U.S. infrastructure.

We made significant progress in implementing our strategy by initiating the second phase of the RemeOs™ Trauma Screw launch in the U.S., bolstered by new distribution and logistics agreements. Additionally, we raised new capital to enhance commercialization efforts and product development.

As a major significant achievement, we received CE mark approval for the RemeOs Trauma Screw product portfolio in January 2025, marking a critical milestone in our pursuit of expanded commercial growth.

In 2024, out net sales increased by 16 percent from the previous year, reaching EUR 4,5 million. The net sales consisted mainly of our Activa products, as the second phase of the launch of RemeOs Trauma Screw begun in 2024 in the U.S. and the CE mark approval allowing the launch in Europe was received in January 2025. Our net sales in Europe increased by 46 percent and in the U.S. 30 percent, while the development in the rest of the world remained relatively stable. Despite a slight dip in our sales margin influenced by China's volume-based procurement policies earlier this year, our margins improved during the last quarter of 2024 due to increased share of sales in the U.S.

Expanding the launch in the U.S.

The launch of RemeOs Trauma Screws in the U.S. yielded excellent patient results and excellent post-healing follow-ups. This success established a strong foundation for entering the second phase of commercialization for RemeOs products in the U.S. In this phase, we will focus on expanding the distribution of the RemeOs Trauma Screw beyond the initial selected group of hospitals to a broader network. In addition to RemeOs products, we are also expanding availability of the Activa product line to the U.S. market.

To support these efforts, we successfully signed two important

new cooperation agreements. In November, we entered into a new logistics agreement with GlobalMed Logistix (GMLx), a leader in healthcare logistics, that operates its own logistics center on the east coast of the United States and has a nationwide network. This agreement ensures high service levels for customers throughout the U.S. market with seamless import and distribution of implants and instrument sets to hospitals. Additionally, we signed an important agreement with Tri-State Biologics (TSB), a leading distributor of medical and surgical products based in greater New York and Boston area. This distributor partnership will enable the efficient sales and distribution of our products to hospitals in one of the most populated areas of the United States.

This distributor partnership will enable the efficient sales and distribution of our products to hospitals in one of the most populated areas of the United States.

A successful share issue

In addition to the commercial progress of the trauma screw, we are excited about the positive results of the RemeOs Spinal Interbody Cage, which received FDA's Breakthrough Device Designation status. To speed-up the commercialization of RemeOs Trauma Screw products and overall product development strategy, including the RemeOs Spinal Interbody Cage, we organized a successful and significantly oversubscribed share issue in November, raising EUR 6 million of funds. We were very pleased with the strong response to the share issue, which reflects the confidence investors have in our vision and strategy.

Long-waited CE mark received

We are extremely pleased that in January 2025, we finally received the CE mark approval for RemeOs Trauma Screws, which not only allows immediate product launch in Europe, but also enables commercialization in non-European countries that recognize the CE mark. The CE mark received includes all RemeOs designs, and a broad indication set. The approval will accelerate the collection of real-world clinical evidence, which will enable the expansion of indications in the U.S., where the current approval is more limited.

With the receipt of the CE mark approval in 2025, we will focus on the launch of the full line of the RemeOs™ products to our customers and existing network of European

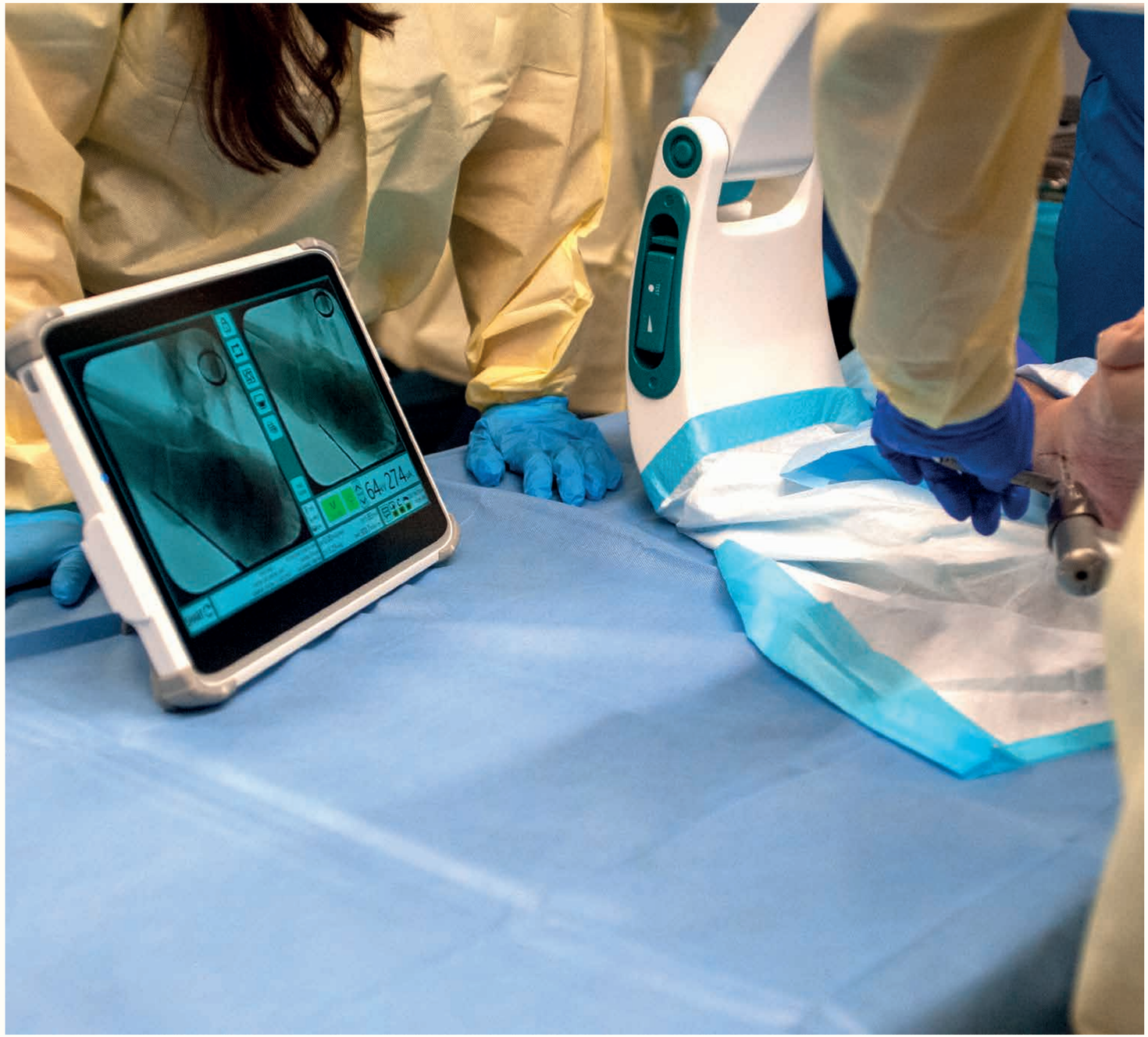
distributors. In the U.S., we wait for new market approvals and maintain a focus on creating market demand with hospitals and surgeons as well as adding additional distributor partners for the U.S. infrastructure. To keep up with the growth and future potential, we will need to further scale up our manufacturing capacity and workforce. To accomplish these plans and achieve our target of generating positive cash flow from operating activities by the end of 2027, we anticipate requiring new funding in 2025.

In summary, I am extremely proud of our progress and excited about the unique opportunities that lie ahead. With the CE mark now received, we are entering a new phase in our growth strategy, and I have full trust in our capabilities to deliver the results. With the support of our dedicated personnel, owners and investors, we are well-positioned to achieve our growth targets and strengthen Bioretec's position as a leader in innovative medical solutions.

> **I am extremely proud of our progress and excited about the unique opportunities that lie ahead.**

Alan Donze
CEO

Alan Donze was appointed as the CEO of Bioretec starting from May 20, 2024



Business & operating environment

Bioretec's business operations cover the entire life cycle of commercialization, from initial product development to dynamic market delivery. Our focus is on building excellence in sales and marketing capabilities.

Our operations are based on robust production processes, certified quality systems, strong customer support and quality by design.

We deliver our innovations to customers with efficiency and effectiveness, driving future growth and high profitability.

Our purpose

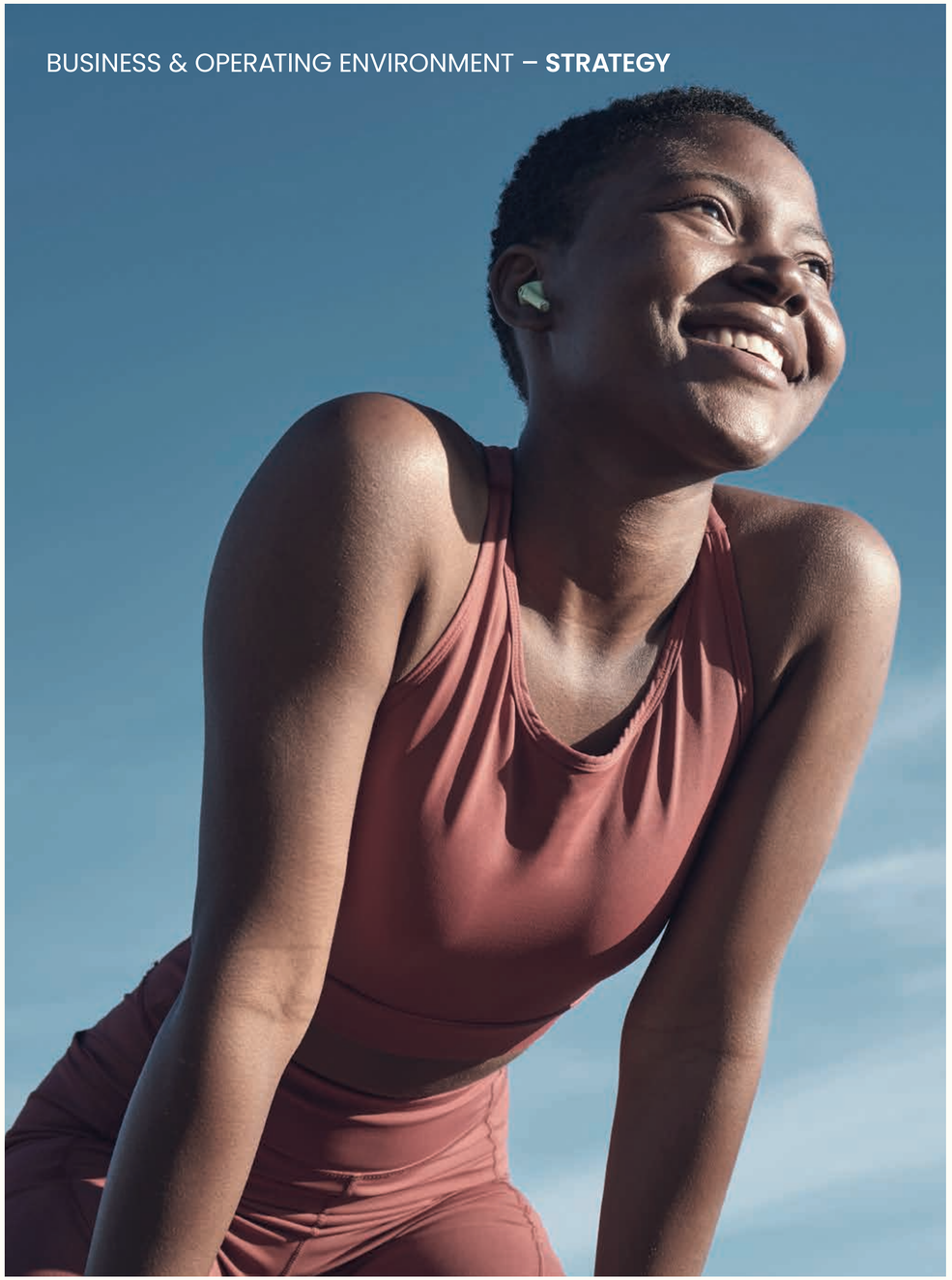
To uncover new possibilities – powered by natural processes – that generate safer and more sustainable healing solutions for patients and the planet.

Our vision

Our vision is a more pure world where technology and biology naturally merge to make healing solutions safer, more reliable and universally accessible.

Our mission

Forging biology and technology, we unlock the potential of the human body to heal itself and return patients to their unique everyday lives with renewed strength and mobility.



Cornerstones of Bioretec's Strategy

Commercialization in Key Markets

Launched in September 2023, RemeOs™ Trauma Screws entered the U.S., the largest single orthopedic trauma product market, initially targeting top-tier academic healthcare centers. The second phase has expanded the distribution network with new partners and we have also strengthened the role of Activa product line in the U.S. market.

In January 2025, after receiving CE-mark approval for the RemeOs products, covering all designs and a broad range of indications, Bioretec commenced product launches in Europe, leveraging its existing distributor network. This approval also facilitates entry into non-European markets recognizing the CE mark.

Expansion of the RemeOs Product Family

Bioretec plans the following future product launches: DrillPin in 2025, staples in 2026, plates in 2027, and the IM-Nail and Spinal Cage post-2028. The development of the RemeOs Spinal Interbody Cage has been accelerated following its designation as a Breakthrough Device by the U.S. FDA in March 2024.

Organizational Excellence

Sustaining high performance and succeeding in a highly regulated, global market demands excellence. Bioretec fosters a culture of innovation that not only drives differentiation and success but also supports retaining current talent and attracting new professionals.

In 2024, we strengthened our team by hiring top talent in the U.S. and Europe, and we continue to expand our workforce this year to drive innovation and growth.

Profitability and Operational Efficiency

Financial Goals: Beyond pursuing sales growth, Bioretec prioritizes achieving high business profitability. The anticipated higher gross margins of RemeOs products, combined with a lean organizational structure and moderate operational expenses, are expected to enhance operational efficiency and profitability in the future.

Scaling up the launch of the RemeOs Trauma Screw in the U.S.

The launch of RemeOs™ Trauma Screws in the U.S. produced excellent patient outcomes, with a significant number of surgeries and successful follow-ups.

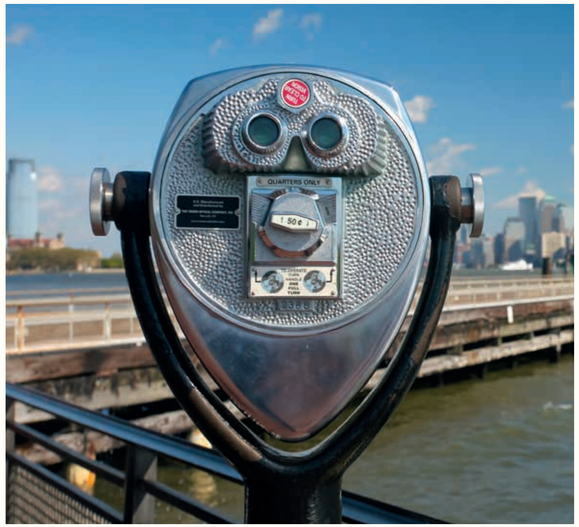
This success demonstrates Bioretec's leadership in innovative absorbable implant technology and sets the stage for the second phase of commercialization of RemeOs products in the U.S. and strong demand among surgeons.

Building on the success of its De Novo U.S. market authorization for the innovative RemeOs Trauma Screw, Bioretec initiated a controlled launch in early 2024 targeting the U.S., the world's largest orthopedic trauma product market. The strategy was meticulously designed to focus on a select group of top-tier academic healthcare centers, specifically chosen for their capacity to gather crucial clinical evidence and lay a robust foundation for broader market adoption. This precise and deliberate approach allowed Bioretec to effectively penetrate and secure a strong foothold in this pivotal market.

Strengthening Market Expertise in the U.S. with Key Strategic Hires

During 2024, Bioretec bolstered its commercialization efforts, particularly in the U.S. market, by appointing Mr. Alan Donze as CEO of Bioretec, bringing with him extensive experience in the commercialization of medical devices in the United States. Furthermore,

Bioretec named Mr. Frank Sarcone as Vice President of Sales for the U.S. Frank brings a wealth of knowledge and experience in managing sales operations for medical devices across the U.S.



> All surgical procedures using RemeOs technology in the U.S. have been successful.

Creating a foundation by gathering surgeon Insights and clinical Evidence

The controlled launch of Bioretec's innovative RemeOs Trauma Screw was strategically implemented to build confidence and methodically collect surgeon feedback and clinical evidence from select hospitals. This initiative has yielded overwhelmingly positive feedback from surgeons, particularly praising the user experience. Impressively, all surgical procedures conducted in the U.S. using the RemeOs technology have succeeded, with every case resulting in fracture healing. Moreover, there have been no reported adverse events or complications during the follow-up period, underscoring the screw's safety and effectiveness.

Expanding Reach: Bioretec Advances U.S. Distribution of RemeOs Trauma Screw

As the controlled launch of the RemeOs Trauma Screw advanced, Bioretec garnered positive feedback, prompting the next phase of its U.S. market strategy. This new phase aims to expand distribution from a select group of hospitals to a broader network across the country. To support these operations, Bioretec has strengthened its logistical capabilities by entering into a new agreement with GlobalMed Logistix (GMLx), a leader in healthcare logistics, for paving the way for more diverse sales

channels including direct sales in the U.S. This partnership is set to ensure customer support and ensure smooth importation and distribution of implants and instrument sets nationwide.

Further expanding its U.S. presence, Bioretec finalized a sales and distribution agreement with Tri-State Biologics (TSB) at the end of 2024. TSB, a top distributor based in New Jersey, will facilitate efficient sales and distribution to major healthcare centers in densely populated regions including Greater New York City, Philadelphia, New Jersey, Connecticut, and Massachusetts. As Bioretec continues to expand its footprint, the company plans to secure additional local sales and distribution agreements to serve civilian hospitals. This strategic expansion is designed to ensure that Bioretec's innovative solutions reach a wider audience, providing essential support to healthcare providers in key U.S. markets.

European Market Entry: RemeOs™ Secures CE Mark Approval

In January 2025, Bioretec achieved a pivotal milestone by securing CE mark approval, enabling market access across Europe and additional countries that recognize the CE mark. This certification confirms compliance with the rigorous Medical Device Regulation (MDR) standards of the European Economic Area. The approval extends to all Trauma Screws within the RemeOs™ product line, thereby supporting a broad spectrum of surgical requirements for both adult and pediatric patients.

Expanding markets of the RemeOs Trauma Screws

- FDA market authorization in the U.S since 2023
- CE mark approval within the EU and non-European countries that recognize the CE mark since January 2025

To lead the imminent product launch across Europe, Bioretec appointed in spring 2024 Ms. Michaela Knigge to manage direct sales activities within the DACH region. With her profound expertise and leadership, Ms. Knigge is poised to enhance market penetration and solidify Bioretec's presence in these crucial Central European markets. This important role is a key component of Bioretec's broader initiative to expand its European operations, utilizing Ms. Knigge's extensive experience in the medical device industry to fulfill the diverse needs of healthcare providers and patients effectively. Additionally, to support direct sales and ensure seamless operations similar to their U.S. strategy with GlobalMed Logistix, Bioretec has partnered with Medddbase. This collaboration will enable logistics and customer support services across Europe, further empowering Bioretec to effectively manage supply chains and customer relations as they expand their reach within this significant market.

The role of the Scientific Advisory Board

Bioretec's dedication to excellence extends beyond its innovative products. Actively involving key opinion leaders in the pre- and postmarket processes, Bioretec guarantees that its solutions meet the evolving needs and expectations of medical professionals. This collaborative approach ensures that surgeons and healthcare professionals remain at the forefront of advancements in the field.

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.

Progress in the expansion into market segments with high potential

1. **U.S. Commercialization of RemeOs Trauma Screws**

- In March 2023, the FDA granted market authorization for the RemeOs Trauma Screw, marking a significant achievement for Bioretec.
- The controlled launch of the screws began in September 2023, initiating their introduction into the U.S. market.
- The ongoing second phase of the launch includes new logistics and distribution agreements to enhance market penetration.

2. **EU Commercialization of RemeOs Trauma Screws**

- Bioretec submitted an application for the CE mark to the European Notified Body in December 2021.
- The CE mark approval process, extended due to the complex regulatory transitions within the EU, concluded successfully.
- In January 2025, Bioretec received the CE mark for the RemeOs Trauma Screw product portfolio, enabling an immediate market launch across Europe.

3. **Development of Other RemeOs Products**

- The RemeOs Spinal Interbody Cage was designated as a Breakthrough Device by the U.S. FDA in March 2024, a recognition that underscores its innovative potential.
- Product development for the RemeOs Spinal Interbody Cage was accelerated in 2024 to fast-track its readiness for market entry.
- Bioretec plans to launch DrillPin in 2025, staples in 2026, plates in 2027, and the IM-Nail and Spinal Cage after 2028.

Expanding the RemeOs™ product range and indications

Bioretec's Research and Development activities in 2024 focused on three key pillars: eduction and training support for sales activities, expanding the RemeOs product offerings, and securing CE mark certification for the entire RemeOs Trauma Screw Product Group.

After the reporting period, in January 2025, we achieved this long-awaited, significant milestone as Bioretec received CE mark for the entire RemeOs Trauma Screw product group for use in pediatric and adult patients. Overall, staying at the forefront of technological advancements and regulatory compliance is the cornerstone of Bioretec's R&D focus.

Product development in the new RemeOs product family

In the first half of the year, Bioretec successfully initiated the planned, controlled rollout of the RemeOs Trauma Screw in the US market. As one strategic aspect of this launch, our R&D team delivered in-depth training and education for U.S. surgeons new to the product. This incorporated several in-person wet lab and cadaver sessions at selected hospitals, complemented by continuous consultations and follow-up with the operating surgeons. The primary goal was to collect both short-term and long-term real-world clinical evidence from various U.S. practitioners to be used in the second phase. To date, we have gathered follow-up data covering 9–12 months, all of which indicate successful outcomes with patients healing within the expected timeframes without complications.

Throughout the year, our R&D team has been focused on expanding the RemeOs Screw portfolio in the U.S., a crucial part of our growth strategy. This expansion is in line with our commitment to the breakthrough device program and aims to enhance our product offerings in the U.S. markets.

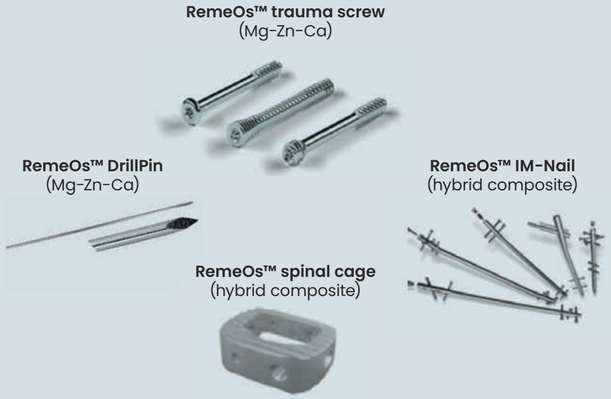
As the year concluded, Bioretec launched another strategic initiative to support the commercialization and usage of its RemeOs and Activa product groups in the U.S. market by developing single-use instrumentation. The U.S. market specifically favors the use of disposable single-use instruments, driven by the need to optimize efficiency due to the high volume of operations and to reduce the risk of infections and cross-contamination. By adopting disposable instruments, we significantly lower the risk of infections and cross-contamination, thereby improving patient outcomes and reducing healthcare costs associated with extended hospital stays and further treatments. This strategic pivot not only meets market demand, but also underscores our commitment to innovation and patient safety, marking a major focus of our research and development efforts in 2024.

CE Mark Approval for RemeOs™ Trauma Screw Product Group drives global expansion

The long-awaited CE mark approval for RemeOs screws, received in January 2025, represents a significant milestone in the evolution of Bioretec's RemeOs products. This approval extends across a wide range of indications, enabling the use of these screws for the fixation of fractures and malalignments in both the upper and lower extremities of adult and pediatric patients, with the exception of the small bones of the hand and forefoot. This comprehensive approval encompasses all cannulated and non-cannulated RemeOs designs, with diameters ranging from 2.0mm to 4.0mm and lengths from 8mm to 50mm.

The breadth of these indications is particularly crucial as it allows Bioretec to immediately offer the RemeOs Trauma Screws to a diverse patient demographic across Europe. Moreover, the CE mark facilitates the basis for local registration in almost all other countries outside the U.S., China, and Japan, significantly enhancing the global reach and impact of our products.

RemeOs™ product pipeline



Product Features & Benefits

- Common surgical techniques
- Versatile indications[1]
- Natural elements Mg-Zn-Ca
- No stress shielding
- Metallic properties
- No need for removal surgery
- Enhanced bone healing
- Resorbs safely in app. 2 – 3 years
- Reduced overall costs

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

The inclusion of pediatric patients in these indications is especially important. Pediatric patients benefit immensely from the use of absorbable implants like the RemeOs screws, which degrade naturally, eliminating the need for a second surgery to remove the implants. This not only reduces the overall risk associated with additional anesthesia and surgery but also minimizes the psychological impact on young patients and their families.

Furthermore, the broad indication coverage in the upper and lower extremities is instrumental in supporting the collection of real-world clinical evidence across a variety of orthopedic conditions, and the possibility for extensive data collection is a stepping stone towards expanding indications in the U.S., where current approvals are more limited. This CE mark approval is not just a regulatory milestone; it is a transformative development that promises to elevate patient care and strengthen Bioretec's position in the global orthopedic market.

RemeOs product pipeline development

Product development across the RemeOs pipeline continued to reach several targets. The clinical study of the RemeOs DrillPin has entered the next phase, with ethical approvals secured for hammertoe indications in adults and distal radius fractures in children. Planned trials are designed to validate the safety and effectiveness of the RemeOs DrillPin in both adult and pediatric populations, covering a broad spectrum of orthopedic indications. As the RemeOs DrillPin is still a non-CE marked product, approvals from national competent authorities are being sought before recruiting the patients.

In March 2024, Bioretec reached a significant achievement when it was granted Breakthrough Device Designation for its RemeOs Spinal Interbody Cage implant by the U.S.

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 bioresorbable polymer matrix combined with two different bioresorbable reinforcements.

Food and Drug Administration. This designation recognizes the product as a breakthrough technology in spinal surgery, specifically designed to restore intervertebral height and facilitate intervertebral body fusion in the cervical spine.

Later in the year, the product development of the Spinal Interbody Cage advanced significantly, with the initiation of the first large animal model trials. These trials are crucial for proving the concept in a biological environment and represent a pivotal step towards bringing this innovative solution to the market. This progression not only highlights Bioretec's commitment to innovation but also strengthens our position in advancing orthopedic care with cutting-edge technology.

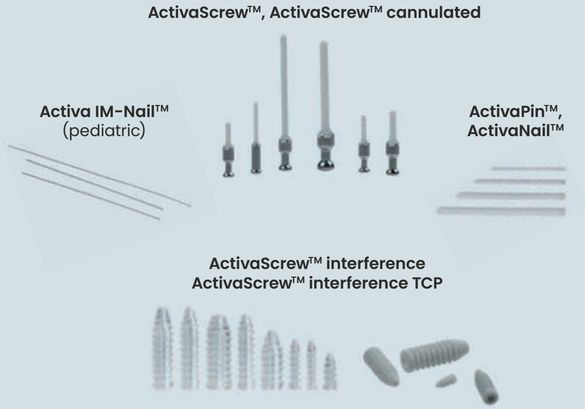
Product development in the current Activa product family

The focus for the Activa product family in 2024 centered on product life-cycle management and the updating of existing registrations across a complex and evolving global regulatory landscape. A key regulatory challenge has been transitioning devices and instruments from the Medical Device Directive (MDD) to compliance under the new Medical Device Regulation (MDR). Additionally, the Activa development team concentrated on completing ongoing clinical investigations.

One significant clinical milestone was the completion of a trial involving the Activa IM-Nail™ for treating pediatric distal radius fractures at a Level 1 pediatric trauma center. This study, which involved 143 patients under 14 years old with unstable distal radial or forearm metaphyseal fractures and open growth plates, compared the Activa IM-Nail™ with traditional percutaneous pinning using metallic Kirschner wires. The findings, presented at the joint Congress of European and North American Pediatric Societies (EPOSNA) in May 2024, demonstrated that the Activa IM-Nail™ group experienced significantly fewer minor complications. Notably, none of the patients in the Activa IM-Nail™ group required secondary interventions for implant removal, in contrast to the K-wire group, where removal was necessary for all children. Furthermore, the Activa IM-Nail™ group had fewer unplanned medical check-ups in the first six weeks post-operation.

Progress was also made in the Post-Market Clinical Follow-up (PMCF) multicenter study focusing on the biodegradable Activa IM-Nail™ for pediatric forearm fractures. The study is close to meeting its patient enrollment targets. Over the past year, surgeons participating in the study published results[1] in the Journal of Clinical Medicine, showcasing that the Activa IM-Nail™ provides stable bone healing and high patient satisfaction. This ongoing study reinforces the effectiveness of the Activa IM-Nail™ in pediatric forearm fracture treatments.

Current **Activa** products



Product Features & Benefits

- No adverse events
- Self-reinforcement technology
- For non-load bearing applications
- Strength retention 8 weeks
- No need for removal surgery
- Fully absorbable
- Designed products for pediatrics
- Absorbs safely in app. 2 years

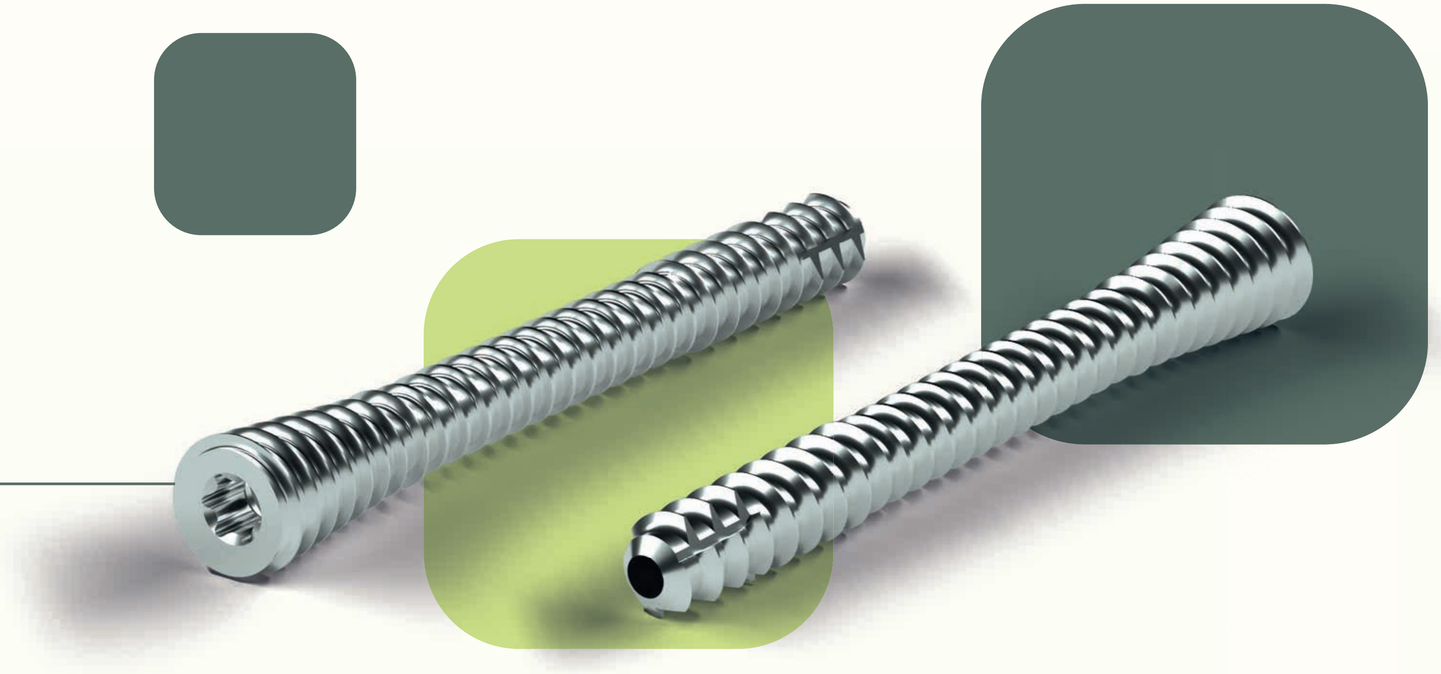
Manufactured of self-reinforced absorbable polymer (PLGA)

[1]Source: J. Clin. Med. 2024, 13(14), 4036; https://doi.org/10.3390/jcm13144036

RemeOs™

Purity and Strength in Healing

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



- Excellent biocompatibility = safe, natural and unique
- Bioactive, osteopromotive properties = enhanced bone growth
- Rapid bone ingrowth, regeneration, and replacement = eliminates removal operations
- Strength retention tailored to match the bone healing = supports the load throughout 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 = compatible with common surgical techniques

*By weight, the alloy contains 0.55% Calcium and 0.45% Zinc.

Case Andrew:

Complex athletic injury managed with absorbable RemeOs™ Trauma Screw

My name is Andrew (42 years) and I have had chronic pain in my right ankle since I sprained it playing football a few years ago. Over the last four years I have had consultations and various imaging studies for my right ankle, and opinions on treatment have varied. Finally, I was diagnosed with a cartilage defect in my ankle which would require surgery on the medial malleolus. The operating surgeon explained the advantages of absorbable metal screws over traditional metals. I considered the absorbable fixation option to be a better option and to avoid a second surgery.

On the day of surgery, I arrived early in the morning and was home by lunch. My surgeon said the procedure went well and that I should be off my feet for six weeks. After six weeks I started physiotherapy without pain and was able to return to work within eight weeks.

After my recovery, I can now jog and go about my day without deep ankle pain. Knowing that there is no more metal in my body after two years gives me peace of mind that my body is back to normal.

Surgeon feedback:

The use of RemeOs Trauma Screw in the operating room (OR) was similar to the use of traditional metal screws. Having the added benefits of bioabsorption and enhanced bone healing, on top of traditional usability, is game-changing.

Testimonials

Dr. David Lin

"RemeOs has allowed me to provide absorbable fixation to my patients, that I personally am comfortable with. In terms of usability, the steps for implantation compared with traditional metal is nearly identical. I have had positive results thus far and plan to continue utilizing this new technology in my practice."

Dr. David Lin, USA
M.D. Podiatry, Foot & Ankle Surgery, DPM FACFAS
Precision Ortopaedics & Sports Medicine

Dr. Robert Leland

"I'm thrilled to be one of the early users of the RemeOs screws and implement their use into reconstructive foot and ankle and orthopedic trauma procedures. The unique screws behave like standard metal screws during surgery and have provided reproducible results similar to standard screws but integrate into bone over time. This is one of the rare truly "new" technologies in Orthopedic Surgery that should have expanding applications over time as the implant portfolio expands."

Dr. Robert Leland, USA
Clinical Assistant Professor in the Department of Orthopedics at the University of Colorado
Member of the Bioretec's Scientific Advisory Board (SAB)

Large and steadily growing market

Bioretec operates in the global orthopedic market, which is estimated to grow to a level of USD 61.9 billion in 2024, up from USD 59.0 billion in 2023, and with an overall estimated 5.0% increase.

In the coming years, the overall growth rate of the global market is expected to be approximately 4%, supported with the convergent tailwinds like aging population and improving technologies.

In 2024, the overall orthopedic market was relatively stable with robust demand for each of the product segments although procedure volumes and seasonality further normalized. Compared to its historical growth rates, trauma was however even overperforming with an estimated growth of 5.9%.

Bioretec's strategic emphasis is on orthopedic trauma products, valued at around USD 9.0 (8.5) billion in 2024, representing 14.6% of the global orthopedic market. One of the key areas for Bioretec is the foot and ankle segment, which stands out as a dynamic and growing market, driven by the various factors such as intensified awareness of foot and ankle health, sports injuries, rising aging population and the increasing prevalence of ankle and foot disorders. Further, minimally

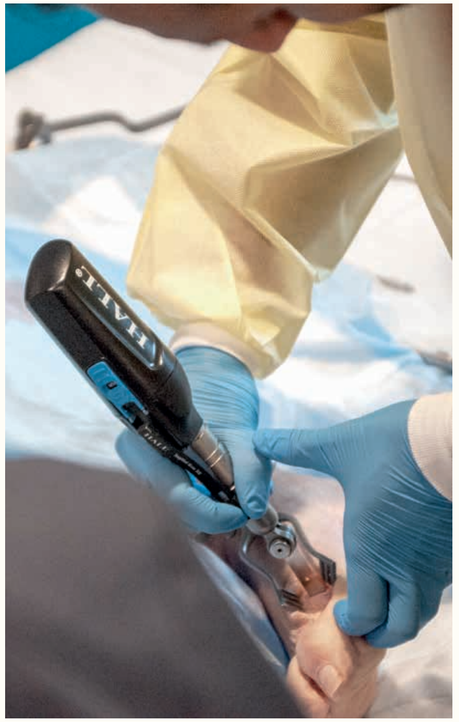
Bioretec's strategic emphasis is on orthopedic trauma products, valued at around USD 9.0 (8.5) billion in 2024.

invasive surgical procedures are becoming more popular for the cure of foot and ankle disorders. The surging demand for foot and ankle devices is generating opportunities for key market players and it will remain a focus area in Bioretec´s short and medium-term product pipeline. Industry forecasts project a robust 7% annual growth rate for the foot and ankle market from 2023 to 2033, potentially reaching a total market value of USD 9.3 billion in 2033. Bioretec is well-positioned to leverage this potential and capitalize on the opportunities in the evolving orthopedic landscape.

Bioretec is well-positioned to leverage foot & ankle market potential and capitalize on the opportunities in the evolving orthopedic landscape.

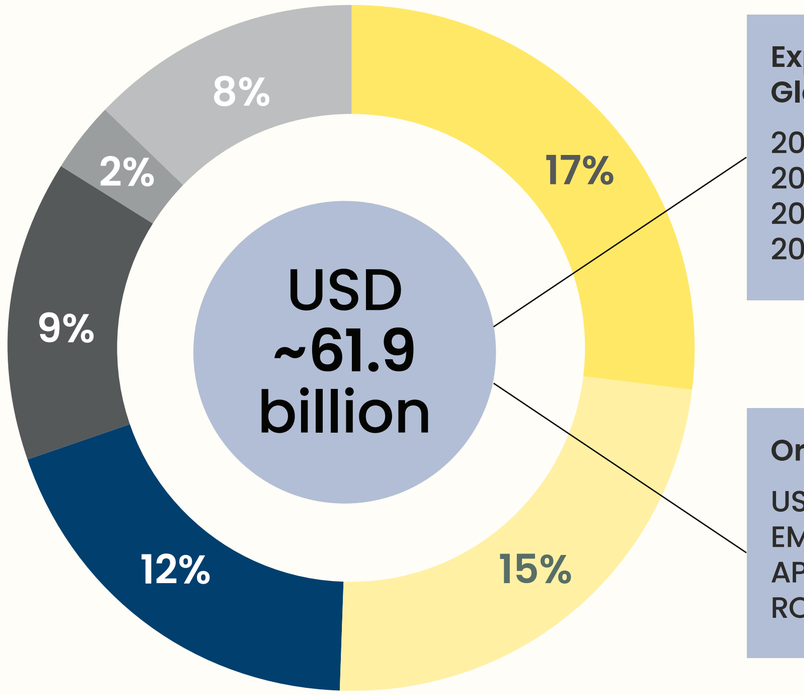
The United States is currently the largest target market for Bioretec, representing a 68% share of the global orthopedic trauma products in 2024. In Europe, the now effective, more stringent Medical Device Regulation (MDR) is reshaping the market landscape. This regulation, more rigorous than its predecessor, the Medical Device Directive, has led to product withdrawals by orthopedic companies, even though the transition deadline has been extended to 2027 or 2028, depending on the device type. Europe as a market remains one of Bioretec's strategic target areas. In China, the transition to volume-based procurement (VBP) has led to lower prices for trauma fixation implants and has been advantageous for domestic Chinese manufacturers. Bioretec continues to closely monitor the VBP progress and its effects to the local market.

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.

Estimated global orthopedic market 2024



Expected Growth of the Global Orthopedic Market

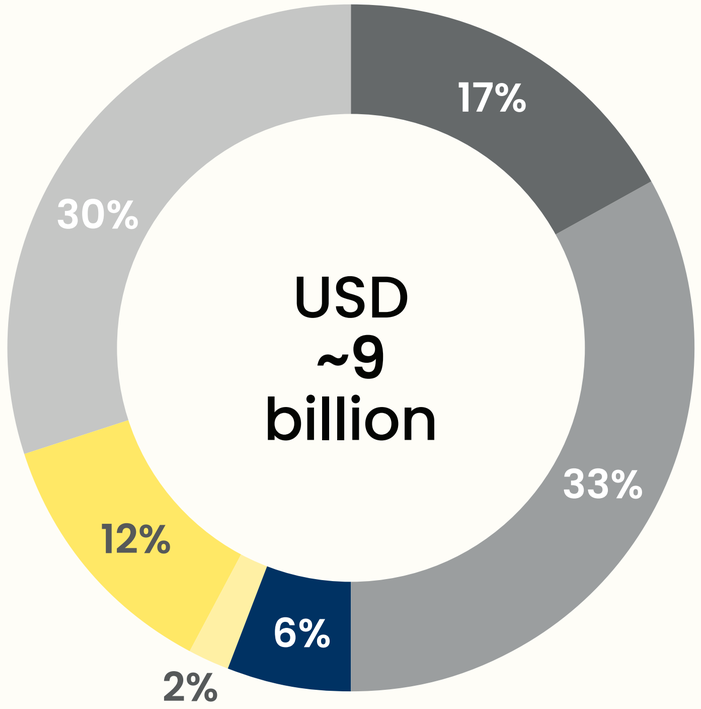
2025 > 64.6 USD billion
2026 > 67.3 USD billion
2027 > 70.1 USD billion
2028 > 72.9 USD billion

Orthopedic market by region

US > 67.1%
EMEA > 18.2%
APAC > 11.4%
ROW > 3.3%

Spine
Trauma
Sports medicine
Orthobiologics
Enabling Technology
Other

Total addressable market for Bioretec's products



Trauma screws
DrillPins/ K-wires
Staples
Plates
IM-Nails
Spinal fusion

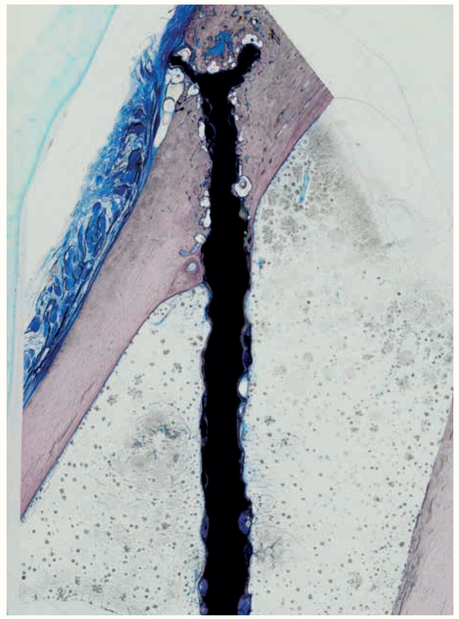
Shaping the Future of Orthopedics: Trends Driving Growth and Innovation

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.

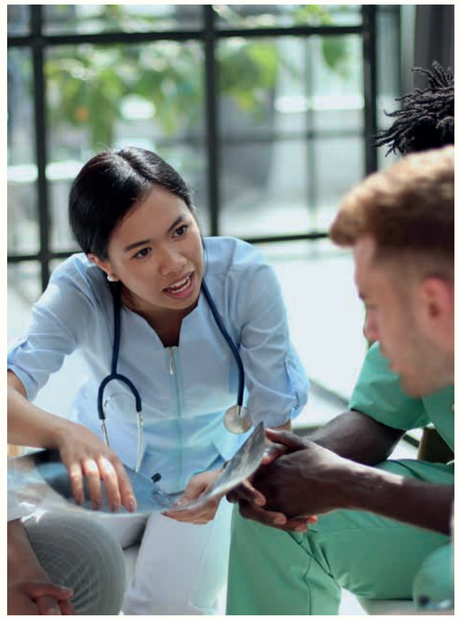


GROWING DEMAND FOR ADVANCED ORTHOPEDIC IMPLANTS

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.

Leading experts supporting throughout the lifecycle of products

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
Specializes in trauma surgery

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
Specializes in trauma surgery

Pediatric advisors

Prof. Dr. Theddy Slongo, Switzerland

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

Dr. Verena Schreiber, USA

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

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)
Specializes in spinal surgery

Prof. Dr. Richard Assaker, France

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

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
Specializes in ankle and foot surgery

Dr. Robert Leland, USA

Member of the SAB since 2023
Clinical Assistant Professor in the Department of Orthopaedics at the University of Colorado
Specializes in ankle and foot surgery

> A key component of Bioretec's development strategy is the invaluable guidance and support of leading experts in the field.

For investors

Information for shareholders

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 6,364,318.67 for the financial period from 1 January to 31 December 2024 be credited in the equity as Profit/loss for previous accounting periods and that no dividend be distributed.

Financial reporting in 2025

In 2025, Bioretec will publish the following financial reports:

- business review for January–March 2025 on Thursday 15 May 2025
- half-year report for January–June 2025 on Thursday 14 August 2025
- business review for January–September 2025 on Thursday 13 November 2025

Financial reports will be available on the company's website, once they are published, at published, at investors.bioretec.com/en.

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 statement bulletins and half-year reports.

Annual General Meeting

Bioretec's Annual General will be held on 21 March 2025 at 11:00 a.m. (Finnish time) at Bioretec's premises in the auditorium of Tampark, at the address Yrittäjänkulma 5, FI-33710 Tampere, Finland.

Bioretec's Investor Relations

Alan Donze
CEO
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alan.donze@bioretec.com

Johanna Salko
CFO
+358 40 754 8172
johanna.salko@bioretec.com

More information for investors at https://investors.bioretec.com/en

10 largest shareholders on 31 December 2024

	Shareholders	Shares	% of shares
1.	Stephen Industries Inc Oy	2,556,370	10.95%
2.	Ilmarinen Mutual Pension Insurance Company	1,750,000	7.50%
3.	Evli Finnish Small Cap Fund	1,003,130	4.30%
4.	Helsingin Yliopiston Rahastot	917,966	3.93%
5.	Elo Mutual Pension Insurance Company	854,622	3.66%
6.	Säästöpankki Small Cap Mutual Fund	800,000	3.43%
7.	Varma Mutual Pension Insurance Company	675,000	2.89%
8.	Danske Invest Finnish Equity Fund	670,841	2.87%
9.	OP-Finland Small Firms Fund	510,000	2.19%
10.	Innovestor Kasvurahasto I Ky	499,945	2.14%
	10 largest shareholders in total*)	**10,237,874**	**43.86%**
	Others	**13,098,984**	**56.14%**
	Total	**23,336,858**	**100%**

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

Share price development 2 January–30 December 2024

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

EUR 2.48
Average price in 2024
(EUR 2.53 in 2023)

EUR 2.40
Closing price on
31 December 2024
(2.40 EUR in 2023)

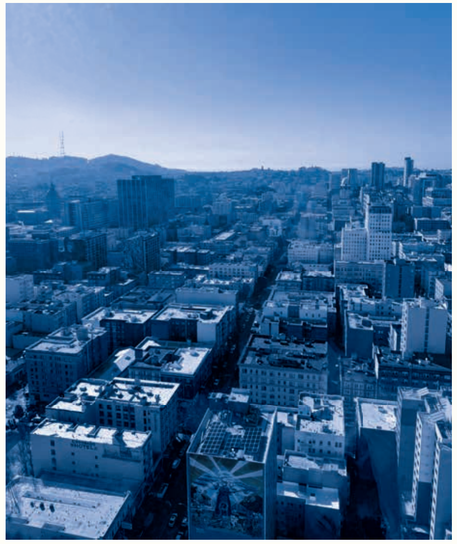
EUR 56.0
Market capitalization on
31 December 2024
(EUR 46.9 million in 2023)

Key Figures

EUR 1,000	FY 2024	FY 2023	Change, %
Net sales	**4,544**	3,906	16.3%
Sales margin	**3,391**	2,810	20.7%
Sales margin (excl. other income)	**3,221**	2,728	18.1%
Sales margin, %	**74.6%**	71.9%	
Sales margin, % (excl. other income)	**70.9%**	69.8%	
EBITDA	**-4,053**	-2,833	43.1%
EBIT	**-4,202**	-3,034	38.5%
Net profit (loss)	**-4,614**	-3,789	21.8%
R&D spend on total costs, %	**28.7%**	25.6%	
Equity ratio, %	**84.9%**	77.3%	
Cash and cash equivalents	**6,289**	6,910	-9.0%
Earnings per share (undiluted)	**-0.20**	-0.19	1.9%
Earnings per share (diluted)	**-0.17**	-0.15	8.7%
Number of shares at the end of the period (undiluted)	**23,336,858**	19,536,858	
Number of shares (diluted)	**27,515,133**	24,908,133	
Personnel at the end of the period	**47**	37	27.0%

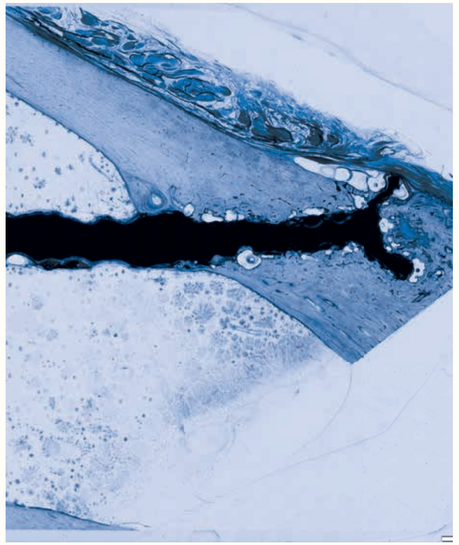
Bioretec as an investment

Bioretec's goal is to improve the quality of life of people worldwide through innovation that can cure bone fractures more sustainably and with fewer surgeries. Bioretec's products are an excellent and clinically proven solution for the treatment of bone fractures.



Attractive market

Global total addressable market of ~USD 9 billion with increasing demand for orthopedic implants.

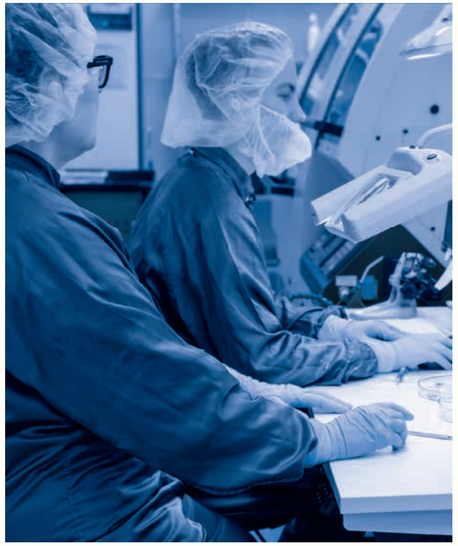


Superior solution for patient healing

Magnesium based absorbable implants promote bone healing and eliminate need for implant removal.

RemeOs™ Trauma Screw has market authorization in the U.S. and CE mark for EU market

RemeOs Trauma Screw is the first and currently only absorbable metal product on the U.S. market.



Strong pipeline for launching additional products in coming years

Market authorizations pave the way for next products.

Experienced management team executing commercialization plan

Supported by top-quality SAB.

Financial targets

2027
Positive cash flow

from operating activities by the end of 2027

2028
Net sales EUR 65 million

by the end of 2028

2030
Net sales > EUR 100 million

by the end of 2030

Bioretec updated in October 2024 the company's product development strategy by accelerating the product development of the RemeOs Spinal Interbody Cage following the granting of Breakthrough Device Designation status by the U.S. Food and Drug Administration on 14 March 2024.

Previous financial targets were net sales of EUR 62 million by the end of 2027 and a positive operating cash flow by the end of 2026.

Board of Directors

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

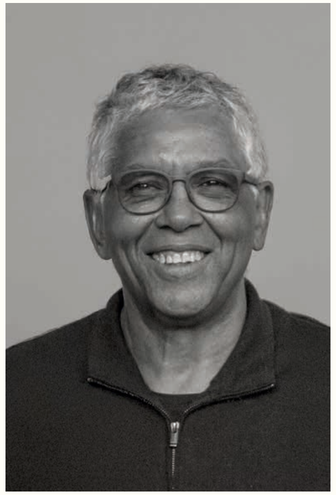
Professional board member

Sarah van Hellenberg Hubar-Fisher
Member of the Board since 2021*

Global Public Health Financing Lead, Johnson & Johnson

Päivi Malinen
Member of the Board since 2022*

Laissa Oy, partner



Michael Piccirillo
Member of the Board since 2018**

Managing Director, VALUGEN GmbH

Kustaa Poutiainen
Member of the Board since 2023**

President and Chairman of the Board, Stephen Industries Inc Oy

More detailed CV information:
bioretec.com

*Audit committee
**Remuneration and nomination committee

Management Team on 31 December 2024

Alan Donze
CEO
since May 2024

Johanna Salko
CFO
since 2021

Timo Lehtonen
CTO since May 2024
CEO until May 2024

Esa Hallinen
Director of Operations
since 2023

Rami Ojala
VP of Sales
since 2022

Mari Ruotsalainen
Director of QA & RA
since 2018

Frank Sarcone
VP of Sales USA
since June 2024

More detailed CV information:
bioretec.com

bioretec

better healing – better life

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