

Bioretec Ltd
Annual Report 2021



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Bioretec Ltd's Financial Statements 2021 is available at www.bioretec.com/investors/investors-in-english/reports-and-presentations



Pioneer in bioresorbable orthopedic implants and reformer of surgical treatment

Bioretec is a globally operating Finnish medical device company that continues to pioneer the application of bioresorbable orthopedic implants. The company has built unique competencies in the biological interface of active implants to enhance bone growth and accelerate fracture healing after orthopedic surgery. The products developed and manufactured by Bioretec are used worldwide in approximately 40 countries.



Our goal is to improve patients' quality of life with an innovation that can heal bone fractures more durably and with fewer surgeries.

Bioretec intends to introduce a new generation of bioresorbable materials with enhanced strength for improved surgical outcome. The new RemeOs™ product line is based on a magnesium alloy and hybrid composite. The RemeOs™ implants are resorbed and replaced by bone, which eliminates the need for removal surgery while facilitating fracture healing. The combination has the potential to make titanium implants redundant and help clinics reach their Value-Based Healthcare targets while focusing on wellbeing of patients through efficient healthcare. With the U.S. and EU market authorization for the first RemeOs™ product expected in 2022, Bioretec is positioning itself to enter the addressable USD 7 billion global orthopedic trauma market and become a game changer in surgical possibilities. Better Healing – Better Life.

Established in 2003 and headquartered in Tampere, Bioretec employed 26 professionals at the end of 2021. In addition, the company's operations are supported by Scientific Advisory Board consisting of distinguished international surgeons. Trading in Bioretec shares commenced on Nasdaq First North Growth Market Finland on 28 September 2021.



Our products bring significant benefits to both the patient and the healthcare system, and thus to society as a whole.



Key figures 2021

2.0 M€
(1.5 M€)
Net sales

1.4 M€
(1.1 M€)
Sales margin

68.7%
(73.5%)
Sales margin, %
of net sales

-2.5 M€
(-1.8 M€)
EBITDA

26
(23)
Employees at
year's end

34.7%
(23.6%)
R&D spend on
total costs, %

Established **2003**

Products sold in **~40** countries

7 CE-marked product families

~240 implants

>300,000 items sold

Building the foundation for the future growth



2021 was a significant year for Bioretec. We took important steps towards commercializing our first RemeOs™ product and completed the listing of our shares on Nasdaq First North Growth Market Finland. Our net sales grew 34% from the previous year.

Commercialization of RemeOs™ trauma screw progressing

Bioretec intends to introduce a new generation of bioresorbable materials with enhanced strength for improved surgical outcome. The new RemeOs™ product line is based on a magnesium alloy and hybrid composite. Market authorization for the first RemeOs™ product is anticipated in the United States in the first half of 2022 and in the European Union in 2022. Bioretec is positioning itself through its product pipeline to enter the addressable USD 7 billion global orthopedic trauma market.

During the spring 2021, the first RemeOs™ product, RemeOs™ trauma screw based on magnesium alloy, was accepted into the Breakthrough Device Designation program by the U.S. Food and Drug Administration (FDA). The designation confirms that the product represents a breakthrough technology, offers significant advantages over existing approved or cleared alternatives and that its availability is in the best interest

of patients. Interactive discussions continue with the FDA, aiming at market authorization approval in the United States. Also in the European Union, Bioretec took a significant step in the commercialization of the product by filing for the market authorization (CE mark) in Europe in December 2021.

In order to ensure a smooth supply of raw materials for its RemeOs™ products, Bioretec entered into a supply agreement with Meotec in Germany for magnesium alloy in January 2022.

Shares traded in Nasdaq First North Growth Market

In 2021, we assessed several options to fund the commercialization of RemeOs™ product family. After the cancelled initial public offering (IPO), Bioretec completed a successful EUR 7.2 million equity funding round in June. The technical listing of Bioretec shares on Nasdaq First North Growth Market Finland was finalized during the third quarter. In September, prior to the technical listing, Bioretec completed a private placement raising EUR 1.7 million of equity capital. The trading in Bioretec shares on Nasdaq First North commenced on 28 September 2021.

Market recovery supporting sales

In 2021, Bioretec's net sales were at an all-time high, EUR 2,003 (1,499) thousand, up by 34% from 2020. The growth was mainly due to the contribution from new distributors and our active sales efforts that resulted in higher sales of Activa products in all territories, but especially in Europe. The growth in net sales was also related to the growing number of surgical procedures in markets where the COVID-19 restrictions had been eased. While the global orthopedic market saw a clear decline in 2020 due to canceled and postponed surgeries, in 2021 the markets already showed some signs of recovery. The main market for Bioretec, the trauma products markets, has suffered the lowest impact from the pandemic, while elective surgeries have declined more severely.

Bioretec's sales margin in 2021 grew by 25% to EUR 1,376 (1,103) thousand, which was 69% (74%) of net sales. Profitability was lower than in 2020, mainly due to a two-month production shutdown and costs related to relocation to our new facility during the summer. Our net profit was affected by the costs related to the cancelled IPO and the funding rounds in June and September, as well as the costs of completed technical listing in September and accrued interest of capital loans. As a result of the commercialization efforts of our first RemeOs™ product, our R&D spend increased to 35% (24%) of total costs.

Making progress in R&D

Bioretec's R&D projects are progressing on schedule, with focus on supporting market authorization for the new RemeOs™ products. The first RemeOs™ product, the trauma screw, has successfully passed the clinical trials. The preliminary results of a 2-year follow-up study are available and will be published as soon as they are finalized. The 3-year follow-up study is currently ongoing. In addition to the trauma screw, we have started product development of three other RemeOs™ implants based on the same metal alloy. The clinical trials for the K-wire are expected to start in 2022 with commercialization anticipated in 2024. The intramedullary nail is expected to be commercialized in 2026 and the spinal cage in 2027 at the earliest.

We are also expanding the application areas of our current product family, the Activa implants. A post-market clinical follow-up study of Activa IM-Nail™ in pediatric diaphyseal forearm fractures continues on schedule. An investigator initiated clinical trial to treat pediatric wrist fractures with Activa IM-Nail™ is also proceeding as planned, with one third of patients treated at the end of 2021.

Increased production capacity supports commercialization

In August, Bioretec relocated to new premises in Tampere, Finland. With expanded production capacity and improved cleanroom

and R&D facilities, Bioretec is now well prepared for the future growth of RemeOs™ products. The new premises also further improve our operational efficiency and logistics. In Europe, the new Medical Device Regulation (MDR) came into force in May. We have therefore updated our operations and procedures to fully comply with the new regulation.

Strengthening competence with new talent

The competence of personnel is an important factor for the long-term success of Bioretec. In 2021, we recruited new members to our management: Johanna Salko joined the company as CFO in February 2021, and Rami Ojala was appointed as Sales and Marketing Director at the end of the year. We also strengthened our competence through other recruitments in functions important for advancing our strategy, such as R&D and product commercialization.

I am proud of the Bioretec team's commitment and efforts in 2021. In a single year, our team was able to carry out the listing of the company's shares on Nasdaq First North, file for the CE mark for our strategically most important product, and actively continue sales and product development activities.



Our net sales increased by 34% thanks to our active sales efforts and the recovering markets.

Targeting EUR 100 million net sales by 2027

Our financial target in the long term is to reach net sales exceeding EUR 100 million in a global USD 7 billion total addressable market by 2027, and to reach positive cash flow from operating activities by the end of 2025.

As a significant share of Bioretec's future revenue is expected to come from products still in the development and commercialization phase, the company expects to incur significant costs relating to further product development resulting in operating losses during the next few years.

In the long term, the orthopedic trauma products are a growing market. The world's increasingly aging population and the increasing number of bone fractures are a global health care challenge. We believe our innovative products can provide an important and valuable solution for orthopedical treatments.

Timo Lehtonen, CEO

Key figures

EUR 1,000	2021	2020	Change, %
Net sales	2,003	1,499	33.6%
Sales margin	1,376	1,103	24.8%
Sales margin, %	68.7%	73.5%	
EBITDA	-2,497	-1,787	39.8%
EBIT	-2,666	-1,925	38.5%
Net profit (loss)	-6,017	-2,259	166.4%
R&D spend on total costs, %	34.7%	23.6%	
Equity ratio, %	50.6%	35.1%	
Cash and cash equivalents	6,621	2,273	191.3%
Earnings per share (undiluted)	-0.43	-0.02	
Earnings per share (diluted)	-0.31	-0.01	
Number of shares at the end of the period*	14,111,858	150,402,068	
Number of shares (diluted)*	19,679,006	218,724,369	
Personnel at the end of the year	26	23	13.0%

*) A reverse split was performed in April 2021, based on which the number of shares was divided by 15.

Highlights of the year

The marketing authorization process for the first RemeOs™ product starts

In March, the U.S. Food and Drug Administration (FDA) granted Breakthrough Device Designation status to the RemeOs™ trauma screw based on magnesium alloy.

Funding round raises EUR 7 million

In June, we announced our intention to be listed on First North Growth Market Finland maintained by Nasdaq Helsinki to finance the commercialization of RemeOs™ products, among other reasons. However, the IPO was cancelled: although it was oversubscribed, the number of subscriptions was insufficient. Instead, we organized a successful funding round with Springvest in June, raising EUR 7.2 million in equity.

New production facilities expand capacity

In August, we relocated to new premises in Tampere, Finland. With expanded production capacity and better cleanroom and product development facilities, Bioretec is now better prepared for the commercialization of RemeOs™ products and future growth. Our operations and procedures have been updated to comply with the Medical Devices Regulation (MDR), which entered into force in May in Europe.

Listing on the First North marketplace

The technical listing on the First North Growth Market of Nasdaq Helsinki was successfully completed in September. Trading in the company shares on First North commenced on 28 September 2021. In September, we also carried out a directed share issue that raised EUR 1.74 million for production investments, the finalization of the marketing authorization process and commercialization of RemeOs™ trauma screw as well as development of other products.

Successful year ended with CE mark filing

In December, we filed for a CE mark for the RemeOs™ trauma screw in the European Union. The CE marking is an important milestone for us in the commercialization of our first RemeOs™ product in the European markets, where we aim to launch the product during 2022.



2021

March

June

August

September

December

A bioresorbable implant supports natural healing

Bioretec develops, manufactures and sells bioresorbable orthopedic implants for the repair of bone and soft tissue injuries in children and adults. Bioresorbable implants help bone to heal and are naturally replaced by bone, eliminating the need for surgical removal operations that are in many cases required when using traditional implants.

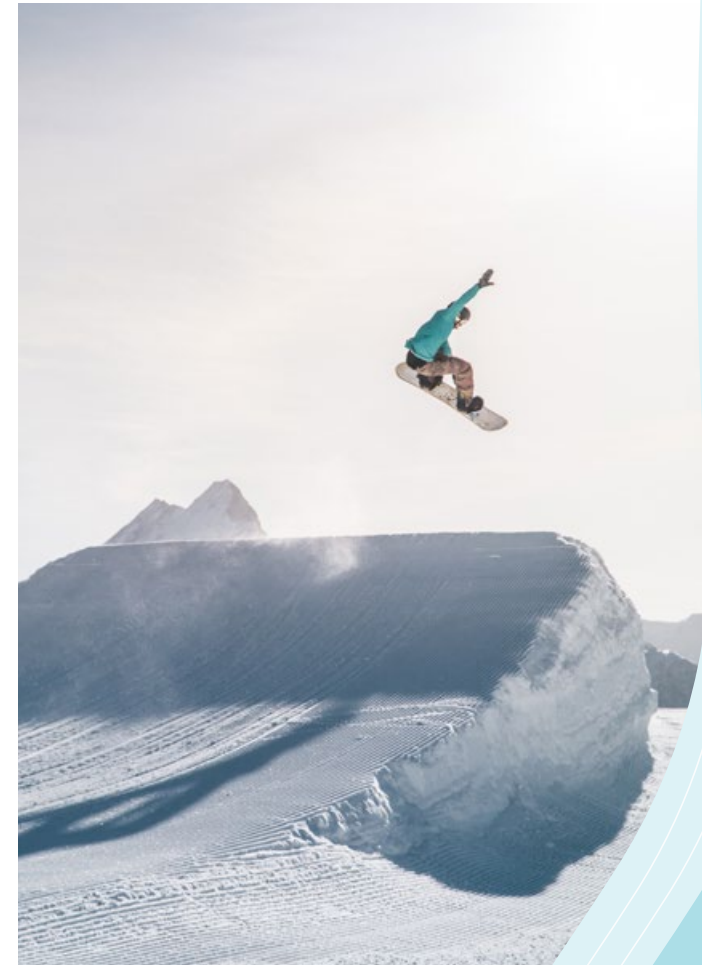
Over the past ten years, more than 300,000 Bioretec products have been sold worldwide. Bioretec has a comprehensive product portfolio of CE-marked products that meet EU directives; 7 product families used for repair of bone and soft tissue injuries, about 240 bioresorbable implants, 4 surgical trays and about 100 surgical instruments. Most of the products in the current product portfolio are also approved by the authorities in the United States and a number of other countries. Our customers are public and private healthcare units and hospital districts, to which products are mainly sold through the distribution network.

Bone needs pressure to heal to its natural strength. Bioretec implants biodegrade slowly and gradually transfer stress to the healing bone. For the patient, this means faster healing, and less pain and side effects. In other words, better quality of life. Bioresorbable implants do not cause stress shielding typical of metallic implants, which can result in the slowing down of bone regeneration and dissolution of bone. If a metal plate bears a load on behalf of the bone, the bone will be structurally weakened because it will not be exposed to normal stress.

Bioretec's **Activa product portfolio**, already on the market, consists of bioabsorbable biopolymer products for pediatric, trauma and sports surgery. The products are used in small bones and soft tissue where high load carrying capacity is not required. One of the key products in the product family is Activa IM-Nail™, the world's first fully bioabsorbable option for pediatric forearm intramedullary nailing. Bioretec aims to extend the indications of the product to the treatment of wrist fractures in children, among others, and a clinical trial is underway to support this.

In addition to the current Activa portfolio, Bioretec is developing new **RemeOs™ product line** based on a magnesium alloy and hybrid composite. The aim is to obtain a marketing authorization for the first product, the trauma screw, on the U.S. market in the first half of 2022 and in the European Union during 2022, after which other products in the product family are anticipated to be commercialized in 2024–2027.

The products in the new RemeOs™ product family will replace some of the Activa products in the future. The use of Activa IM-Nail™ in children is likely to continue also after the launch of the RemeOs™ product family.



Our products: Bioresorbable orthopedic implants

Current Activa product family

- Bioabsorbable biopolymer implants
- For applications that do not require high load carrying capacity
- Already sold in about 40 countries

Future RemeOs™ product family

- Bioresorbable implants for applications requiring higher load carrying capacity
- Comprised of magnesium, zinc and calcium
- Natural materials for the human body with metal properties and strength
- Commercialization of the first product will start in 2022

Activa IM-Nail™ (pediatrics)



Activa Nail™



Activa Pin™



ActivaScrew™



ActivaScrew™ ACL



Trauma screw (2022)



K-wire (2024)



Intramedullary nail (2026)



Spinal cage (2027)

The RemeOs™ product family, on the eve of commercialization, is suitable for increasingly diverse applications

The first product in the new RemeOs™ product family, the trauma screw, is a bioresorbable magnesium-based implant for the treatment of bone injuries in adult patients. The future products in the RemeOs™ product family are also suited for applications requiring higher load carrying capacity, such as fractures of large bones, as the strength properties of bioresorbable metal used in RemeOs™ product family are significantly higher than those of Bioretec's current Activa polymer products. This allows the RemeOs™ implants, depending on the product, to be used for new applications, such as the femur, tibia or spine, where it has not previously been possible to use bioresorbable implants.

RemeOs™ trauma screws are based on bioresorbable metal alloy that is comprised of natural components present in the human body, such as magnesium, calcium, and zinc, which support the formation of new bone and the healing process. The alloy does not contain rare earth metals foreign to the body, present in some of the other bioresorbable metal products on the market.

The components of the alloy allow the formation of new bone and support the fixation of the bone. The healing process is supported by the gradual biodegradation of the implant. Unlike when using conventional non-bioresorbable implants, the load on the healing bone increases gradually so that the bone reaches its natural strength. In many cases, the traditional non-bioresorbable metal implants leave bone with areas that are never fully healed after removal surgery. Instead, the new bone is filled with soft and scar tissue. This can make the bone weaker and more vulnerable to new fractures. RemeOs™ implants completely degrade in the human body in about 2 to 3 years, depending on implant size.



The new metal alloy is based on natural materials that are also present in the human body and doesn't contain rare earth metals foreign to the body.



Bioresorbable RemeOs™ products eliminate the need for removal surgery and provide significant benefits to patients, healthcare system and society



Benefits to patients

- The quality of life improves: the patient avoids the implant removal surgery and the complications typically associated with it, such as pain, nerve damage, inflammation and the risk of 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 product does not contain rare earth metals, the patient does not need to worry about their long-term effects and possible negative reactions in the body, as with traditional implants.



Benefits to healthcare units

- The use of bioresorbable products allows surgeons to focus on value-creating treatment procedures instead of implant removals.
- The products do not require re-training of surgeons, as the use and methods are consistent with traditional metal implants.
- Unlike traditional titanium and steel implants, bioresorbable implants do not interfere with magnetic resonance imaging (MRI).



Benefits to society

- The use of the resources in the healthcare system becomes more efficient: society avoids the costs of removal surgeries, which can cost a country the size of Germany more than EUR 1 billion per year in treatment and lost productivity (in 2014, source: Destatis, Robert Koch Institute, Federal Health Report).

Activa IM-Nail™ – the first bioresorbable intramedullary nail on the market for the patient-friendly treatment of children’s forearm fractures

Bioretec’s Activa products offer excellent treatment options for pediatric patients. Activa IM-Nail™ made of biopolymer is the world’s first fully bioresorbable intramedullary nail for treatment of pediatric forearm fractures. Traditional metal implants must be removed from the child’s body to avoid disturbing the natural growth of the bone. Activa IM-Nail™ is bioresorbable, so pediatric fractures can be treated without implant removal surgery. The flexibility of the Activa IM-Nail™ allows the implant to be installed from a place that is not detrimental to the child’s growth plate. Therefore, the installation and use of the implant will not interfere with the child’s growth.



“We started using the Activa IM-Nail™ at our clinic in September 2020. We have operated on 35 children with the new technique, and we have been able to monitor seven of them post-operatively for over a year. The results confirm that the technique works and that there have been no significant complications for the patients. The parents and children are very pleased that there is no need for a second surgery to remove the implant. Today, the Activa IM-Nail™ is our ward’s primary technique for treatment of children’s forearm fractures.”

Dr. Marcell Varga, Budapest, Hungary

Hungarian Sara is an 11-year-old gymnast and top athlete who fractured both of her forearms. The fractures were repaired with Activa IM-Nail™ implants. Six months after the surgery, Sara returned to the gymnastics floor and continued to prepare for competitions just like before. Since there was no need for a second operation to remove the implant, nothing interfered with her training. One year after the surgery, she finished third in her age group in national competitions.

On the right is Sara a year after surgery:



We aim to provide industry-leading scientific evidence on the benefits and safety of our products

Bioretec invests heavily in research and development, focusing on supporting the commercialization of the new RemeOs™ product family and further developing and expanding the indications of select products in the existing Activa product family. The products are developed together with the company's international Scientific Advisory Board, whose members are distinguished medical experts and surgeons. In 2021, research and development spend increased by 96% to EUR 1.4 million, accounting for 35% of Bioretec's total costs.

The new RemeOs™ product family

Bioretec is developing a new RemeOs™ product line based on a magnesium alloy and hybrid composite (i.e. a combination of magnesium alloy and biocomposite), introducing a new generation of strong bioresorbable materials for enhanced surgical outcomes.

The first RemeOs™ product, trauma screw based on magnesium alloy for the treatment of bone fractures in adult patients, has passed clinical trials in 2018–2020. The first-year follow-up study in 2020 yielded promising results in safety and usability: There were no complications and complete consolidation of fractures was achieved in all patients in the trial at 12 weeks. The screw was found to be an excellent and safe alternative to non-bioabsorbable metal screws and eliminating the need for implant removal surgery. The results of the two-year follow-up study will be published soon and a third-year follow-up study is currently on-going.

Bioretec expects to receive a marketing authorization for the RemeOs™ trauma screws in the United States during the first half of 2022 and in the European Union during 2022. In December 2021, Bioretec filed for CE mark for the RemeOs™ magnesium screw in the EU. In addition, Bioretec is developing three other products for the RemeOs™ product family: K-wire, intramedullary nail and cage. These products are currently in the product development, feasibility and research phases, with the goal of commercializing them one product at a time in 2024–2027.

Current Activa product family

Bioretec also has ongoing product development projects to develop the properties and extend the indications of its current product, Activa IM-Nail™, used in the treatment of pediatric patients. Activa implants are bioabsorbable implants made of PLGA (poly-lactide-co-glycolide copolymer), which has a long history in medical use. An investigator initiated clinical trial to treat pediatric wrist fractures (Distal Radius) with Activa IM-Nail™ is currently ongoing and the post-market clinical follow-up study of Activa IM-Nail™ in CE-marked indication of pediatric diaphyseal forearm fractures continues as planned.



The development of the RemeOs™ trauma screw has progressed to the third-year follow-up study.



Key product development projects

Product	Indication	Previous studies	Status
RemeOs™ trauma screw of magnesium alloy	Adult patients' bone injuries	<ul style="list-style-type: none"> • Pre-clinical trials 2015–2018 • Clinical trial 2018–2020 • One-year follow-up study 2020 • Two-year follow-up study completed in 12/2021 	<ul style="list-style-type: none"> • Clinical trials completed successfully • Three-year follow-up study ongoing • Aiming for commercialization in 2022 • CE mark application filed in the European Union in December 2021
RemeOs™ K-wire of magnesium alloy	Arms, legs, elbows, wrists	<ul style="list-style-type: none"> • Preliminary studies 2015–2018 	<ul style="list-style-type: none"> • In product development phase • The goal is to start clinical trials in 2022 and commercialization in 2024
RemeOs™ intramedullary nail of hybrid composite based on magnesium alloy and biocomposite	Fractures of long bones (femur, tibia, forearms, clavicle and fibula) in adults	<ul style="list-style-type: none"> • Preliminary studies completed in 2020 	<ul style="list-style-type: none"> • Feasibility study in progress • The goal is to start clinical trials in 2023 and commercialization in 2026
RemeOs™ cage of hybrid composite based on magnesium alloy and biocomposite	Fusion of the vertebrae of the spine, i.e. intervertebral disc repair		<ul style="list-style-type: none"> • Study in progress • The goal is to start preclinical trials in about 2023–2024 and clinical trials in about 2025–2026 • Commercialization will start in 2027 at the earliest.
Activa IM-Nail™ of biopolymer (PLGA)	Pediatric forearm fractures	<ul style="list-style-type: none"> • Clinical trials in 2010–2017 	<ul style="list-style-type: none"> • Post-market clinical follow-up (PMCF) of CE-approved indications in progress in several European countries
	Expanding the indications to pediatric wrist fractures		<ul style="list-style-type: none"> • Investigator-initiated clinical trial began in the first half of 2021 and is progressing according to plan. 37% of pediatric patients treated by 31 December 2021.

FDA's Breakthrough Device Designation status emphasizes the potential of RemeOs™ trauma screw

The U.S. Food and Drug Administration (FDA) granted Breakthrough Device Designation status to RemeOs™ trauma screw in March 2021.

The status can be granted to products that

- Provide more effective treatment for life-threatening or irreversibly debilitating diseases
- Represent breakthrough technologies for which there are no approved alternative products
- Offer significant advantages over existing products, such as the potential to reduce the need for hospitalization, improve the patients' quality of life and facilitate self-care, or
- Alternatively represent a form of treatment that is in the best interest of patients.



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

Bioretec's goal is to improve people's quality of life globally, with an innovation that can heal bone fractures more durably and with fewer surgeries.

Vision

Bioretec's vision is to become a globally recognized medical device company and a leader in bioresorbable metal implants.

Mission

Bioretec's mission is to introduce novel, innovative, high-quality bioresorbable surgical devices which improve patient healing, safety and cost-efficiency in clinical care.

Bioretec's strategy

Expansion into market segments with high potential

1

Commercialization of the RemeOs™ trauma screws

In the United States:
• through own sales organization



In Europe:
• through distributors



Development and commercialization of other products in the RemeOs™ product family

- K-wire 2024
- Intramedullary nail 2026
- Cage 2027-

During H1/2022

During 2022

2024-2027

2

Maintaining world-class talent and capabilities in the organization

We endorse a winning culture, which commits the current employees to the company and attracts new talent with a high level of competence.

3

Focus on achieving high profitability

We aim to improve profitability through operational efficiency and lean organization.

Financial targets

**Revenue
> EUR 100
million**

in a global USD 7 billion
total addressable market
by 2027

**Positive
cash flow
from operating
activities**

by the end of 2025

Market trends



Ageing population

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



Increasing number of traumas

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



Favorable reimbursement policies

Changes in reimbursement policies and improved insurance coverage, in particular in the United States, support market growth.



Increasing demand for advanced orthopedic implants

Removal surgeries of existing non-bioresorbable implants pose risks to patients and cause costs to the healthcare system.



Increasing need for customer-centric solutions

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

Large and steadily growing market

Bioretec operates in the global market for orthopedic products, which in 2020 had a turnover of approximately USD 47.5 billion. In 2020, the global orthopedic market declined by around 11% due to uncertainty brought on by the COVID-19 pandemic, widespread restrictions, and surgical cancellations. The effects of the pandemic continued throughout 2021. However, there were some signs of recovery, and forecasts for 2021 estimate orthopedic market turnover of USD 54.5 billion in 2021, up by 15% from the previous year.

The main market segment for Bioretec's products is the orthopedic trauma products market, which in 2020 was approximately USD 7.1 billion globally, or 15% of total orthopedic products market. The pandemic has also affected the

development of the trauma products market, but the impact has been lower than for other orthopedic products. Forecasts for 2021 expected the trauma market to amount to USD 7.6 billion, up by 7.7% from 2020. From 2016 to 2023, the market for orthopedic trauma products is expected to grow annually by about 3%. The biggest driver of the market for trauma products is the increase in the number of fractures, especially as the proportion of the elderly population increases.¹

Bioretec's addressable market is expected to grow significantly with RemeOs™ products

Bioretec estimates that with the launch of four RemeOs™ products (trauma screw, K-wire, intramedullary nail and cage), the company's addressable market will grow to USD 7 billion in 2027.

Global addressable market for new RemeOs™ products in 2019²

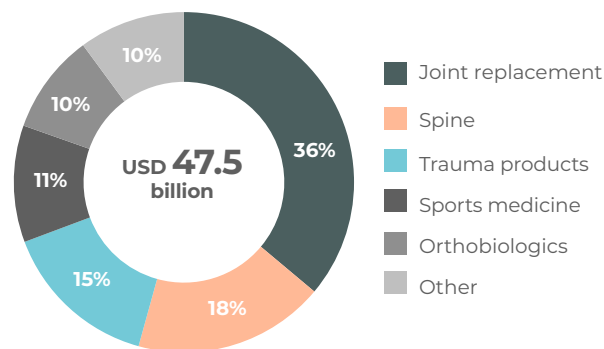
- trauma screw about USD 1.2 billion
- K-wire about USD 100 million
- intramedullary nail about USD 2.7 billion
- cage about USD 2 billion

According to Bioretec, the trauma screw market is a low-risk market, which is why Bioretec has decided to commercialize the trauma screw first.

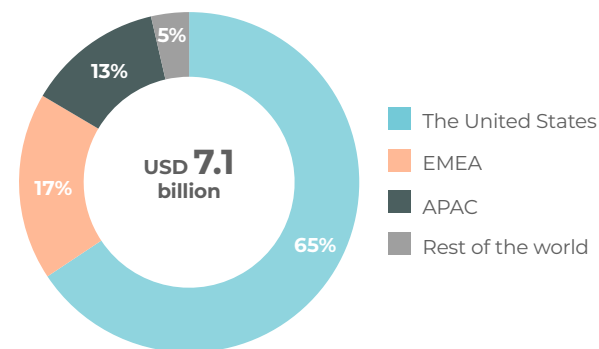
North America is the biggest market

The biggest geographic market for orthopedic products is the United States, accounting for USD 4.6 billion and 65% of global market in 2020. The United States is expected to remain the most important market also in the future.

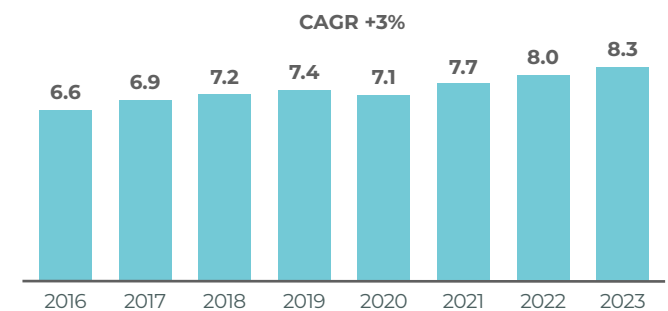
Orthopedic product market by segments in 2020¹



Orthopedic trauma product markets by area in 2020¹



Orthopedic trauma products market development in 2016–2013, USD billion¹



¹) Source: The Orthopaedic Industry Annual Report 2021, Orthoworld Inc.

²) Source: GlobalData Report 2020, Trauma Fixation (Orthopedic Devices) and Global Interbody Fusion Cage Market Research Report 2021, QYResearch.

Use of bioresorbable materials becomes more common

The most common materials for manufacturing orthopedic trauma screws are currently titanium and stainless steel. Due to its low cost, stainless steel has a strong position in the emerging markets in particular. Bioretec uses bioresorbable materials, such as biometals, biopolymers and biocomposites, and combination of biometals and biocomposites in its current and future products, and these materials are expected to become more common in developed countries. Bioretec estimates that bioresorbable trauma screws will be competitive on the market not only compared to existing bioresorbable trauma screws, but also to titanium and steel implants. In the United States, titanium accounted for 55%, stainless steel for 30% and bioresorbable materials for 15% of the trauma screw market in 2019.¹

¹) Source: GlobalData Report 2020, Trauma Fixation (Orthopedic Devices) -Global Market Analysis and Forecast Model (COVID-19 market impact).

²) Source: The Orthopaedic Industry Annual Report 2021, Orthoworld Inc.

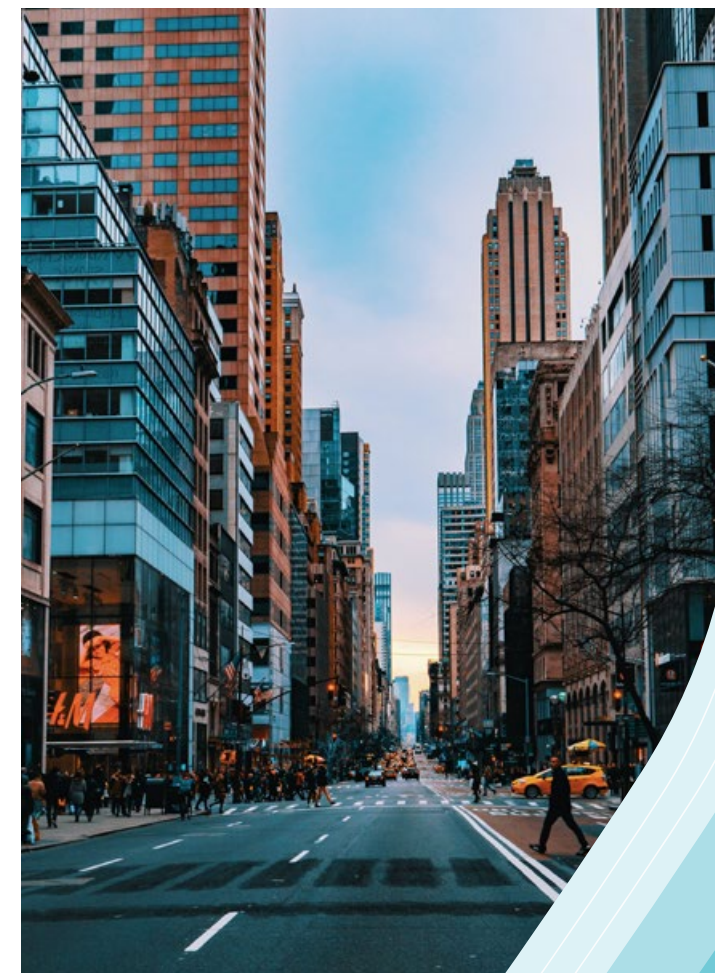
Small companies as innovators

While there are hundreds of companies operating in the market for orthopedic products, the market is largely concentrated in a small number of large companies. Seven of them had a revenue of more than USD 1 billion in 2020, totaling approximately USD 31 billion. In trauma products, the biggest players on the market are largely the same companies.²

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



Our goal is to be the first to commercialize bioresorbable metal implants free of rare earth metals in the U.S. market. As far as we know, the largest companies in the orthopedic products market do not have bioresorbable metal implants under development or in the approval process.



Information for shareholders

Bioretec Ltd's share is listed on First North Growth Market Finland 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.

Listing of shares

Bioretec applied for its shares to be listed on the Nasdaq First North Growth Market Finland marketplace maintained by Nasdaq Helsinki in September 2021. Trading in the company's shares began on 28 September 2021. The listing was carried out as a technical listing.

The aim of the listing was to increase the general interest of investors, customers, surgeons and business partners in the company, to improve the company's attractiveness to potential employees and engage company's current employees, and to enable a liquid market for the company's shares and a broader and more diversified investor base in the future.

Share issue

In September 2021, Bioretec Ltd completed a private placement, in which the company issued a total of 580,000 new shares to institutional investors and a limited number of other investors. The subscription commitment for the share issue was conditional on the listing of the company's shares on the First North Growth Market Finland marketplace maintained by Nasdaq Helsinki. The share subscription price was EUR 3.00 per share.

Bioretec raised EUR 1.74 million of funds in the share issue. The purpose of the share issue was to strengthen the company's financial position and enable investments in the company's production, the completion of the RemeOs™ trauma screw marketing authorization process and the commencement of commercialization measures, as well as the product development of new products.

Dividend policy

The company's business has been unprofitable so far. Due to this, it has not distributed any dividends, and will not distribute dividends prior to 1 December 2023. In the near future, the company expects to 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 is linked to the company's results of operations and financial position.

Distribution of profit

The Board of Directors proposes to the General Meeting of shareholders that no dividend be paid for 2021.

Financial reporting in 2022

Bioretec will publish its Half-year report for January–June 2022 on 12 August 2022. 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 bulletin and half-year reports.

Annual General Meeting

Bioretec's Annual General Meeting is planned to be held on Wednesday, 13 April 2022. Bioretec's Board of Directors will summon the meeting at a later date.

Bioretec's Investor Relations

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More information for investors at
www.bioretec.com/investors



EUR 2.94

Closing price on
28 September
2021

EUR 2.70

Closing price on
30 December
2021

38.1 M€

Market capitalization
on 31 December
2021

10 largest shareholders on 31 December 2021

	Shareholder	Shares	% of shares
1.	Innovestor Growth Fund I Ky	1,292,650	9.16%
2.	Helsinki University Funds	917,966	6.50%
3.	Eakr-Aloitusrahasto Oy	606,370	4.30%
4.	Orion Pension Foundation	464,622	3.29%
5.	VR Pension Fund	442,068	3.13%
6.	The Farmers' Social Insurance Institution Mela	332,868	2.36%
7.	Kela, the Social Insurance Institution of Finland	292,769	2.07%
8.	Törmälä Pertti Olavi	278,468	1.97%
9.	Rajamäki Olli Valtteri	240,972	1.71%
10.	Frontier Liquidity Oy	188,104	1.33%
	10 largest shareholders in total*	5,056,857	35.82%
	Other	9,055,001	64.18%
	Total	14,111,858	100%

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

Share price development on 28 September–30 December 2021

Closing price, EUR



Marketplace: Nasdaq First North Growth Market Finland

Trading code: BRETEC

ISIN code: FI4000480454

Management Team on 1 January 2022



Timo Lehtonen
CEO since 2019



Minna Ahlstedt-Soini
Production Director since 2015,
member of the Management
Team since 2013



Kimmo Lähteenkorva
Chief Technology Officer
since 2017



Johanna Salko
CFO since 2021



Rami Ojala
Sales and Marketing Director
since 1 January 2022

(Lauri Hokkanen was Sales and Marketing Director and member of the Management Team until 31 December 2021).



Mari Ruotsalainen
Director, QA & RA since 2018,
member of the Management
Team since 2004

” More detailed CV information:
[www.bioretec.com/investors/
investors-in-english/governance](http://www.bioretec.com/investors/investors-in-english/governance)

Board of Directors on 31 December 2021



Tomi Numminen

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

Main occupation: professional board member



Michael Piccirillo

Member of the Board since 2018

Main occupation: Managing Director, Symgery Inc. and VALUGEN GmbH



Hans Rosén

Member of the Board since 2018

Main occupation: Managing Director, Theradex (Europe) Ltd



Pekka Simula

Member of the Board since 2020

Main occupation: Managing Director Meles Consulting Ltd



Sarah Hubar-Fisher

Member of the Board since April 2021

Main occupation: Global Public Health Financing Lead, Johnson & Johnson



More detailed CV information:
www.bioretec.com/investors/investors-in-english/governance

Bioretec's strengths



RemeOs™ products are an innovative and clinically proven effective solution for the treatment of bone fractures, currently in the commercialization phase.



RemeOs™ trauma screw has been granted Breakthrough Device Designation status by the FDA in the United States. Bioretec expects to receive a marketing authorization for the trauma screw in the United States during the first half of 2022 and in Europe during 2022.



The United States is the world's largest single market for orthopedic trauma products, with a large and steadily growing addressable market for the products.



RemeOs™ trauma screw reduces the need for surgeries and the risk of complications and provides significant cost savings compared to traditional metal implants.



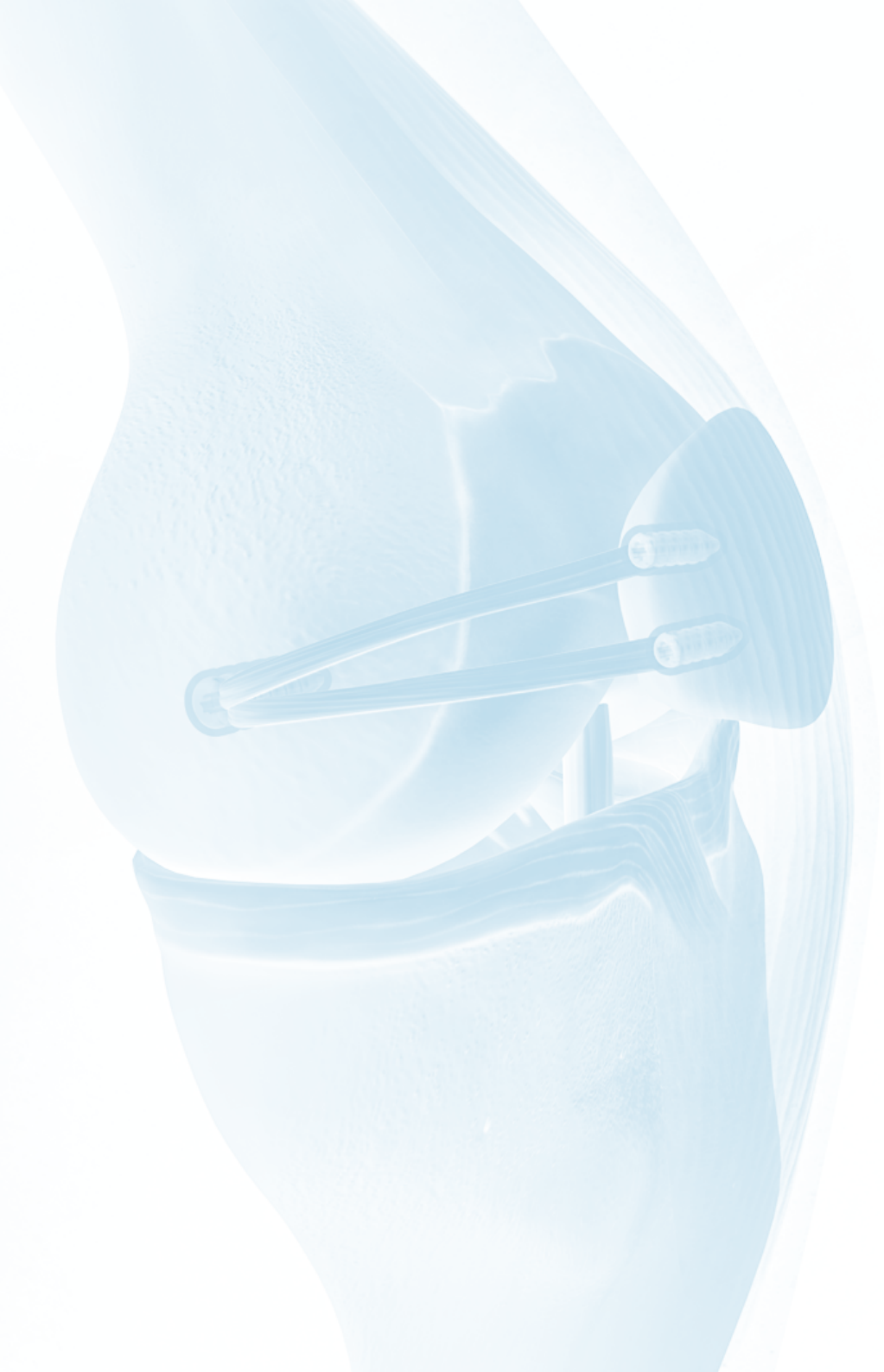
Bioretec has been operating since 2003, and the company's current products are sold in approximately 40 countries.



The operations are scalable, enabling high profitability in the future.



The company has experienced management and a global Scientific Advisory Board implementing a clear commercialization plan.



bioretec

better healing – better life

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www.bioretec.com