

Financial Statements Bulletin 2022 (unaudited)

H2

We are delighted about the sales growth and look forward to future approvals

JULY–DECEMBER 2022 IN BRIEF

- Net sales increased by 59% and amounted to EUR 1,520 thousand (7-12/2021: EUR 956 thousand).
- Sales margin was EUR 1,121 (598) thousand or 73.8% (62.6%) of net sales, with year-on-year growth of 87%.
- Net profit (loss) for the period amounted to EUR -1,049 (-3,226) thousand.
- Earnings per share (undiluted) were EUR -0.07 (-0.23).

JANUARY–DECEMBER 2022 IN BRIEF

- Net sales increased by 47% and amounted to 2,942 thousand euros (1-12/2021: 2,003 thousand euros).
- Sales margin was EUR 2,139 (1,376) thousand or 72.7% (68.7%) of net sales, with year-on-year growth of 55%.
- Net profit (loss) for the period amounted to EUR -2,416 (-6,017) thousand. Net loss for the comparison period was affected by the costs related to the equity funding expenses and the impact on profit of accrued interest on capital loans totaling EUR 3.35 million.
- Earnings per share (undiluted) were EUR -0.17 (-0.43).
- The Board of Directors proposes that no dividend will be paid for 2022.

KEY EVENTS IN 2022

- In January 2022, Bioretec entered into a supply agreement with Meotec GmbH in Germany for magnesium alloy raw materials for bioresorbable RemeOs™ products.
- In May 2022, Bioretec announced having submitted a market authorization request for its bioresorbable RemeOs™ magnesium screw in the U.S. In October 2022, Bioretec estimated that the market authorization in the U.S. would be granted in April 2023.
- In September 2022, Bioretec announced the approval of the company's hybrid composite material patent application in Europe.
- In November 2022, Bioretec updated its estimate of the timing for approval of the CE mark for the RemeOs™ trauma screw in the European Union. The company estimated that obtaining market authorization would move to 2023. The delay was due to the general European medical device regulation (MDR) situation causing a significant increase in timelines for all product CE certifications. It did not relate to any RemeOs™ product-specific issue.
- Sales increased during H1 2022 by 36% (compared to H1 2021) as full-year 2022 increased by 47% (against the comparison year 2021).

This financial statements bulletin is unaudited. The full-year 2021 figures are audited.

KEY FIGURES

EUR 1,000	H2 2022	H2 2021	Change, %	FY 2022	FY 2021	Change, %
Net sales	1,520	956	58.9%	2,942	2,003	46.9%
Sales margin	1,121	598	87.4%	2,139	1,376	55.4%
Sales margin, %	73.8%	62.6%		72.7%	68.7%	
EBITDA	-916	-1,340	-31.6%	-2,112	-2,497	-15.4%
EBIT	-1,006	-1,438	-30.0%	-2,292	-2,666	-14.0%
Net profit (loss)	-1,049	-3,226	-67.5%	-2,416	-6,017	-59.8%
R&D spend on total costs, %	25.3%	22.1%		28.1%	34.7%	
Equity ratio, %	55.2%	50.6%		55.2%	50.6%	
Cash and cash equivalents	1,223	6,621	-81.5%	1,223	6,621	-81.5%
Earnings per share (undiluted)	-0.07	-0.23	-67.5%	-0.17	-0.43	-59.8%
Earnings per share (diluted)	-0.05	-0.16	-67.4%	-0.12	-0.31	-59.7%
Number of shares at the end of the period (undiluted)	14,111,858	14,111,858		14,111,858	14,111,858	
Number of shares (diluted)	19,608,126	19,679,006		19,608,126	19,679,006	
Personnel ¹	28	26	7.7%	28	26	7.7%

¹Number of personnel at the end of the period

Excited about receiving the market approvals in the U.S. and Europe

Highlights of the year included the U.S. market approval application submission of the game-changing bioresorbable RemeOs™ trauma screw to enable entry into the world's largest orthopedic market, supported by excellent in vivo and clinical evidence of the unique properties of the RemeOs™ technology, and a nearly 50 percent increase in sales of the Activa product family, resulting in record high sales for 2022, close to EUR 3 million.

At the beginning of 2023, the RemeOs™ trauma screw continues on the path to being the first bioresorbable metallic orthopedic implant in the US market, the world's largest and most profitable market.

We began the year 2022 with a strong focus on our first-ever U.S. De Novo application request for the bioresorbable magnesium alloy RemeOs™ trauma screw initially based on the Breakthrough Device Designation- status, received in 2021. After submitting the De Novo Request last May, we delivered clarification request responses to the FDA (U.S. Food and Drug Administration) within their required deadlines in the last quarter of the year. Based on this progress and the FDA has, according to its internal guidelines, a maximum of 90 days to make a decision, we expect to have market authorization in the U.S. in April 2023.

We are excited about receiving the market approvals not only in the U.S. but also in Europe during the forthcoming year, as the submission of the EU market authorization (CE mark) application for RemeOs™ trauma screws took place right at the end of 2021. We expect the European CE mark approval to be received later in the year as the number of applications resulting from the change in regulations (MDR) has overwhelmed the notified bodies and the average approval time is currently around 18 months.

The first half of the year already showed strong sales with 36% growth year-on-year, and the trend even improved during the second half yielding a substantial 59% growth. Our full-year 2022 net sales grew approximately 47 percent from the previous year. I am very pleased with the net sales growth of our current Activa products, as well as the fact that profitability remained approximately at the same level as in 2021, despite it was affected by the increase in raw material, logistics, and energy costs caused by inflation and the global political situation.

One main growth driver has been our investment in long-term partnerships with our distributor network and key opinion leaders (KOLs). Our renewed education and product training programs for customers in both legacy and new markets e.g., Israel, have been a key element of our relationship development. Additionally, post-coronavirus pandemic resource shortages have been a driving force for increased demand for bioresorbable products that reduce both the number of surgeries and hospital stays. The competitive pricing of our products along with our good customer relationships have furthermore contributed to sales growth in several market areas.

A big appreciation belongs to our committed team for enabling and generating growth. Our team has worked tirelessly to further strengthen our existing customer relationships, acquire new customer relationships, and ensure deliveries correspond to the significantly increased demand.

As a result of the growing demand for our products, we have during the year 2022 focused on increasing the capacity and capability of the production. In addition, we are currently evaluating alternative financial means to support our continued growth, the expansion of our production capacity, and most importantly, the commercialization of our new technology.

We are entering 2023 with positive momentum after our first full year as a listed company. The year 2022 accelerated our transition to becoming one of the leading companies in the growing orthopedic bioresorbable trauma product market with our submission for both the CE mark (Europe) and FDA approval (US) of our innovative and novel RemeOs™ bioresorbable metal screw. When cleared, RemeOs™ will, based on the company information, be the first bioresorbable metallic trauma screw in the U.S. market. We are genuinely excited about preparing for the launch of our products and the start of sales in these markets this year.

In addition to our team, I would also like to warmly thank our customers, partners, and investors for their trust in Bioretec.

Timo Lehtonen, CEO

Accelerated growth in Activa sales

In 2022, Bioretec's revenue had strong 47% year-on-year growth and continued the trend set during previous years. One of the key drivers for the sales growth was Asia, where the demand for bioresorbable products is increasing, and we gained new hospitals as customers.

Bioretec's net sales in 2022 showed robust growth in the global healthcare market situation where the impact of the coronavirus pandemic seems to be decreasing except in China. The healthcare staffing shortage has been reflected in the demand for the company's products, especially in Scandinavia. Net sales amounted to an all-time high in Bioretec's history, EUR 2,942 (2,003) thousand, an increase of 47% compared to 2021. The net sales consisted of revenue related to current Activa products. Bioretec's Activa products are sold in approximately 40 countries globally through distributors. Net sales grew mainly in Asia, but particularly in the second half of the year also in Europe. The growth is driven by the increased demand for bioresorbable products, the wider customer base, and active sales with increased training for the distributor network.

Sales by geographical area

In January–December 2022, 39% (50%) of net sales came from Europe, 2% (5%) from the U.S., and 59% (45%) from the rest of the world. Net sales in Europe increased 12% year-on-year due to increased market interest gained together with new distributors in Europe. Healthcare staffing shortages hindered the growth, especially in the Scandinavian market. In Russia, since the 24th of February 2022, Bioretec continued only to fulfill the existing contractual sales obligations. Sales in Russia in 2022 were EUR 333 (278) thousand. Net sales in the United States decreased by 34% due to the ongoing restructuring of the distribution network. Net sales in the rest of the world increased by 95%. The growth was mainly driven by China, with an 80% contribution to the net sales in that geographical area. The growth in China was mainly due to the increased number of new customers using Bioretec's bioresorbable products.

EUR 1,000	H2 2022	H2 2021	Change, %	FY 2022	FY 2021	Change, %
Europe*	601	487	23.4%	1,138	1,012	12.4%
U.S.	36	46	-21.4%	63	96	-34.0%
Rest of the world	883	423	108.7%	1,741	895	94.6%
TOTAL	1,520	956	59.0%	2,942	2,003	46.9%

*Russia included in Europe

Market development ¹

Bioretec operates in the global market for orthopedic products, which in 2021 had a turnover of approximately USD 53.6 billion and is expected to have surpassed USD 55.5 billion in 2022, growing +3.4% versus 2021. While the industry faced a third year of disruption, its 2022 growth closely reflects the pre-pandemic average growth rate even with macroeconomic challenges, such as supply chain disruption, inflation, and staffing shortages, which are forecasted to persist into 2023.

The main market segment for Bioretec's products is the orthopedic trauma products market, which in 2021 was approximately USD 7.8 billion globally. It is expected to have reached USD 8 billion in 2022, with a growth of +3.8%. While the trauma market was the most insulated segment from the effects of the pandemic, its 2022 growth is slightly below pre-pandemic rates. The fast-growing foot and ankle segment remains the outlier in the trauma market, showing double-digit growth rates. In orthopedic trauma products, the largest geographic market is the United States as of 2021 (65%); the United States is expected to remain the most important market also in the future. The out-of-US environment will pose significant challenges for companies. Transfer to Volume-based procurement at the national level in China impacted drastic price cuts in joint replacement, spine, and trauma, and it is expected more segments to come under national tenders. So far, bioresorbable products like Bioretec's have been outside of Volume-based procurement. Additionally, looming EU MDR deadlines are forcing companies to consider which products to prioritize and keep on the market.

In the long term, the market for orthopedic trauma products is expected to continue to grow. From 2022 to 2025, the market for orthopedic trauma products is expected to grow annually by about 4.3%. 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. Additionally, obesity and certain diseases (e.g., osteoporosis and diabetes) increase fracture risk. The world's aging population and the growing number of bone fractures are global health challenges. We believe that our innovative products can provide an important and valuable solution for orthopedic treatment.

¹Source for market forecasts: Orthoworld: The Orthopedic Industry Annual Report 2022 and Orthopedic Market 2022 Projections & 2023 Outlook.

Supporting commercialization

As Bioretec's main short-term target is to commercialize the RemeOs™ trauma screws in the United States and Europe, the research and development concentrated on registration activities and achieving market authorizations in these geographical areas. Additionally, the company received positive results from ongoing clinical trials, further validating the benefits of Activa products.

Product development in the new RemeOs™ product family

The RemeOs™ implants are made from bioresorbable metal (magnesium-calcium-zinc). They are resorbed and replaced by bone and eliminate the need for implant removal surgery while facilitating fracture healing. The first RemeOs™ products, trauma screws based on magnesium alloy, have passed a clinical trial with excellent results and are showing complete radiological disappearance of the screws in the follow-up study up to three years without product-related adverse events and complications. In May 2022, Bioretec submitted a market authorization request in the U.S. for its RemeOs™ trauma screw. During the De Novo request process, the FDA has requested clarifications and additional justifications for the submitted application. As per FDA internal guidelines for the De Novo process, Bioretec delivered the required additional information within the deadline. After the receipt, the FDA has a maximum of 90 days to decide. Therefore, the expected approval date was transferred to April 2023.

In December 2021, Bioretec applied for a CE mark for the RemeOs™ trauma screw in the European Union and by then, estimated the approval time to be around 12 months. Due to the reasons not related to the company or the product, caused by the prolonged approval times in the EU (average 18 months) resulting from the additional workload of the transition from the MDD (Medical Device Directive) to the MDR (Medical Device Regulation) exceeding the capacity of the Notified Bodies to handle the applications. Bioretec is therefore still waiting for feedback from its Notified Body on the main sections of the submitted application. For these reasons, the company's target to have a CE mark has been postponed from 2022 to 2023, and more precise estimations cannot be given at this stage. On 9 December 2022, the EU Council decided to support a proposal to postpone the MDR deadlines of the legacy devices to a later date (from the earlier date of 26 May 2024) to ease the workload of the Notified Bodies. The Commission and the EU Council may move forward with an amendment at the beginning of 2023 to extend the MDR deadline.

In addition to trauma screws, Bioretec is also developing three other products for the RemeOs™ product family: RemeOs™ DrillPin (K-wire), intramedullary nail, and cage. These products are currently in the product development, applicability, and research phase, and the company intends to commercialize them one product at a time in 2024–2027. When the innovative and novel RemeOs™ bioresorbable metal -material is approved by the FDA during the current De Novo application, we expect a more straightforward regulatory process with other upcoming products utilizing the same material, but simply with new indications.

Product development in the current Activa product family

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

The bioresorbable children's intramedullary Activa IM-Nail™ showed convincing interim results in the Post-Market Clinical Follow-up study for the treatment of children's forearm fractures. Forearm fractures are a common¹ injury in children and adolescents. Often, the traditional metal implant is removed after the fracture has healed. The published² interim results of the international Post-Market Clinical Follow-up (PMCF) study indicated that the use of Activa IM-Nail™ in diaphyseal pediatric forearm fractures with regard to various study objectives, including the clinical outcome, postoperative complications, and refracture rate, is equal to the standard titanium procedure but with a benefit of avoiding secondary implant removal operation. The study assesses the safety and effectiveness of Activa IM-Nails™ as part of the surgical treatment of dislocated forearm fractures in children between 3 and 13 years of age. A prospective multicenter study is continuing as planned in many European countries to ascertain the rate of refracture and to determine the subjective benefits of Activa IM-Nail™ for patients, their parents, and other caregivers. At the end of the year 2022, approximately 60% of targeted pediatric patients had been treated.

During 2022, an investigator-initiated multi-center clinical trial was ongoing to treat pediatric wrist fractures (Distal Radius) with Activa IM-nail. Distal radius fractures are very common in pediatric patients, and severely displaced fractures may require surgical intervention. The current best practice surgical (golden standard) method is percutaneous titanium or stainless steel Kirschner wires (K-wire) osteosynthesis that is followed by immobilization and often removed with a second intervention. The ongoing clinical study is executed as a comparative trial with the K-wires. The study is running according to the plan, and at the end of the year 2022, approximately 73% of targeted pediatric patients had been treated.

The need to prioritize healthcare resources and additionally the healthcare sector manpower shortages may also impact Bioretec's ongoing and forthcoming clinical trials. Updates will be provided when applicable.

¹ Children, DOI:10.3390/children9050754

² Musculoskelet Surg. 2021; 105(3): 225–234. Published online 2020 Oct 14. doi: 10.1007/s12306-020-00684-6

Group financial development

NET SALES, PROFITABILITY, AND FINANCIAL PERFORMANCE

Net sales and sales margin

In July–December 2022, Bioretec Group's net sales grew 59% year-on-year, amounting to EUR 1,520 (956) thousand.

Net sales for January–December 2022 amounted to EUR 2,942 (2,003) thousand, an increase of 47% from the comparison period. The growth was mainly due to the increased demand in Asia.

Bioretec's sales margin in July–December 2022 grew by 87% to EUR 1,121 (598) thousand or 74% (63%) of net sales.

Sales margin in January–December 2022 grew by 55% to EUR 2,139 (1,376) thousand. The sales margin was 73% (69%) of net sales. Increased production volumes as a result of production efficiency measures increased efficiency and improved profitability, despite increased material and logistics costs and increased price competition. The comparison period was burdened by the cost impact of the relocation of premises and the production shutdown.

Operating expenses

In July–December 2022, Bioretec Group's total operating expenses grew 4% year-on-year and amounted to EUR 2,127 (2,037) thousand.

In January–December 2022, Bioretec Group's total operating expenses grew almost 10% year on year, amounting to EUR 4,430 (4,042) thousand. The increase was due to, among other things, an increase in personnel costs due to the increased number of personnel and the need for additional research required by the ongoing market authorization application to the United States.

The Group's R&D expenses in 2022 totaled EUR 1,245 (1,401) thousand, down 11% from the comparison period. The reason for the decrease is that the comparison period included the costs of RemeOs™ clinical studies. In addition, in accordance with the company's recording practice, the company recorded a total of EUR 215 thousand of the separate costs of obtaining market authorizations during the financial year in intangible assets on the balance sheet. In addition to new product development, R&D expenses also include expenses related to the current Activa product portfolio.

EBITDA and net profit (loss)

Bioretec Group's EBITDA in July–December 2022 amounted to EUR -916 (-1,340) thousand. Net loss for the period was EUR -1,049 (-3,226) thousand.

EBITDA in January–December 2022 amounted to EUR -2,112 (-2,497) thousand. The main reason for the increase was the improved absolute sales margin as a result of the increased demand. Net loss for the period was EUR -2,416 (-6,017) thousand, which was significantly lower than in the comparison period. The financing costs in the comparison period included equity funding expenses amounting to approximately EUR 3,350 thousand as well as the cumulative interest impact of the capital loan.

FINANCIAL POSITION AND CASH FLOWS

On 31 December 2022, the Group's equity ratio was 55% (51%), and the Group's total liabilities were EUR 1,566 (4,243) thousand. Interest-bearing liabilities amounted to EUR 713 (1,977) thousand, including EUR 703 (22) thousand of long-term liabilities. During the financial year 2022, the company paid EUR 1,221 thousand of the capital of convertible bonds and capital loans on the balance sheet at the end of 2021, and a total of EUR 2,735 thousand including interest. The company negotiated with Business Finland an extension of the loan payment period having capital loan terms and located in the balance sheet at the end of the financial year 2022. The company estimates that the capital and related interest will be repaid in spring 2024 at the earliest. The capital is presented in full in the long-term liabilities of the balance sheet, and interest is not recorded in the income statement as the legal requirements for the payment of capital loan capital and interest are not met.

At the end of the financial period, the Group had EUR 1,223 (6,621) thousand of cash and cash equivalents and money market deposits.

In January–December 2022, cash flow from operating activities totaled EUR -2,360 (-2,387) thousand. Cash flow from financing activities, EUR -2,778 (7,128) thousand, consisted mainly of a total payment of convertible loans and loans for product development from Business Finland and the related interest. The comparison period included equity funding income and expenses.

In January–December 2022, the Group's capital expenditure totaled EUR 260 (393) thousand. Investments during the period consisted mainly of costs capitalized in intangible assets related to market authorization processes in the EU and the U.S. The capital expenditure of the comparison period was mainly related to Bioretec's relocation to the new office and factory premises.

FINANCIAL TARGETS

The company's financial targets are intact:

- reach revenue of more than EUR 100 million in a global over USD 7 billion total addressable market by 2027; and
- reach positive cash flow from operating activities by the end of 2025.

PERSONNEL AND MANAGEMENT

At the end of 2022, Bioretec had 28 (26) employees. The average number of employees from 1 January to 31 December 2022 was 26 (24). Salaries and other personnel expenses in 2022 totaled EUR 2,353 (2,186) thousand.

On 31 December 2022, the members of Bioretec's Management Team were Timo Lehtonen (Chief Executive Officer), Johanna Salko (Chief Financial Officer), Minna Ahlstedt-Soini (Production Director), Rami Ojala (Sales and Marketing Director), Kimmo Lähteenkorva (Chief Technology Officer) and Mari Ruotsalainen (Director of QA & RA). Rami Ojala joined the Management Team on January 1, 2022. There were no changes in the composition of the Management Team during the review period.

BOARD OF DIRECTORS

On 31 December 2022, Bioretec's Board of Directors had five members: Tomi Numminen (Chairman of the Board), Michael Piccirillo, Sarah van Hellenberg Hubar-Fisher, Päivi Malinen, and Pekka Simula.

AUDITOR

Bioretec's auditors are Authorized Public Accountants Ernst & Young with Erika Grönlund, Authorized Public Accountant, as the responsible auditor.

ANNUAL GENERAL MEETING AND BOARD AUTHORIZATIONS

Bioretec's Annual General Meeting was held on 13 April 2022 in Tampere, Finland. The Annual General Meeting resolved to approve the financial statements for the financial year 2021 and resolved to discharge from liability the members of the Board of Directors and the CEO for the financial period from 1 January to 31 December 2021. The Annual General Meeting approved the Board of Directors' proposal not to pay dividends.

The Annual General Meeting resolved that the Board of Directors shall have five members. The Annual General Meeting resolved that Tomi Numminen, Michael Piccirillo, Sarah van Hellenberg Hubar-Fisher, and Pekka Simula were re-elected as members, and Päivi Malinen was elected as a new member of the Board of Directors for a term starting at the end of the Annual General Meeting and expiring at the closing of the 2023 Annual General Meeting. At the Organizing meeting, held after the Annual General Meeting, the Board of Directors elected Tomi Numminen as Chairman of the Board.

It was resolved that the following remuneration will be paid to the members of the Board of Directors for the term beginning at the end of the Annual General Meeting and ending at the end of the 2023 Annual General Meeting: EUR 2,500 per month for the Chairman of the Board of Directors and EUR 1,500 per month for the members of the Board of Directors. Additionally, it was resolved that the company may extend the consultancy agreement with Tomi Numminen in respect of consulting services related to the company financing and commercialization of the company's products in the United States. The consultancy fee payable pursuant to such agreement is EUR 7,500 per month.

The Annual General Meeting elected Authorized Public Accountants Ernst & Young Oy as the auditor of the company for a term ending at the close of the Annual General Meeting of 2023. Ernst & Young Oy has appointed Erika Grönlund, Authorized Public Accountant, as the responsible auditor. The auditor will be compensated as reasonably invoiced.

Authorization of the Board of Directors to resolve on the issuance of shares and special rights entitling to shares

The Annual General Meeting resolved to authorize the Board of Directors to resolve on the issuance of shares, as well as the issuance of option rights and other special rights entitling to shares pursuant to Chapter 10 of the Finnish Companies Act, as follows:

Under the authorization, up to 5,000,000 shares (including the new shares to be issued based on the special rights) can be issued, representing approximately 35 percent of all outstanding company shares at the Annual General Meeting record date of April 1, 2022.

The shares or special rights entitling to shares can be issued in one or more tranches, either against or without payment. The shares issued under the authorization can be new shares or shares in the company's possession.

The authorization can be used for the financing or execution of acquisitions or other business arrangements, to strengthen the balance sheet and financial position of the company, for implementing the company's share-based incentive plans, or for other purposes determined by the Board of Directors.

Under the authorization, the Board of Directors may resolve upon issuing new shares, without consideration, to the company itself.

The Board of Directors was authorized to resolve on all terms for share issues and granting of special rights entitling to shares in the company. The Board of Directors is authorized to resolve on a directed share issue and issuance of special rights entitling to shares according to the shareholders' pre-emptive rights and/or in deviation from the shareholders' pre-emptive right, provided that there is a weighty financial reason for the company to do so.

The authorization is valid until the end of the next Annual General Meeting, however, no longer than until 30 June 2023. The authorization revoked previous unused share issue authorizations except for the authorization granted by the Annual General Meeting held on 26 June 2020 authorizing the Option Program 2020–1. The authorization for Option Program 2020-1 has remained valid until December 31, 2022.

Granting option rights to the members of the Board of Directors

The Annual General Meeting resolved, according to the proposal of the Board of Directors, to grant Option Rights in accordance with the terms of the stock option plan 2020–1 entitling in the aggregate to up to 106,666 new shares to Board members Sarah van Hellenberg Hubar-Fisher and Päivi Malinen.

SHARES AND RELATED PROGRAMS

Bioretec has one share class. Each share has equal voting rights, and all shares of the company provide equal rights to the dividend. The company's shares are listed on the Nasdaq First North Growth Market Finland marketplace.

On 31 December 2022, Bioretec had a total of 14,111,858 (14,111,858) shares. The share capital was EUR 3,749 (3,749) thousand. Bioretec does not hold its shares. During the year 2022, the average number of shares was 14,111,858 (12,069,331), and 14,111,858 (12,429,858) during the second half of 2022. When calculating the average number of shares, the 2020 year-end number has been adjusted with the reverse split impact, which took place in April 2021. The average number of shares (diluted) during the year 2022 was 19,643,566 (17,130,315) and 19,608,126 (19,389,003) during the second half of 2022.

There were 252 trading days in the review period. A total of 2,109,933 (1,088,877) shares were traded during the period, and the total value of the shares traded was EUR 4,379,089 (3,002,118). The highest price of the share was EUR 3.07 (3.59), and the lowest price was EUR 1.32 (2.49). The volume-weighted average price was EUR 2.31 (2.76) and the closing price at the end of the period was EUR 1.41 (2.70). In accordance with the closing price, the combined market value of the shares was approximately EUR 19.8 (38.1) million.

Shareholders

Bioretec's shares are in the book-entry system maintained by Euroclear Finland, and Euroclear Finland maintains Bioretec's official shareholder register. At the end of 2022, Bioretec had a total of 2,519 (2,235) registered shareholders, of whom 89% (88%) were private individuals. There were 777,143 (809,881) nominee-registered and foreign-owned shares, which was 5.5% (6%) of all shares and votes. The largest shareholders and shareholders by sector are available on the company's website at <https://bioretec.com/investors/investors-in-english/share/shareholders>.

At the end of 2022, the members of Bioretec's Board of Directors owned a total of 12,690 (6,000) company's shares. The CEO did not own any of the company's shares (at the end of 2021, 0 shares). Other members of the Group's Management Team owned a total of 5,624 (6,291) company shares. Consequently, the company's executive management held 0.13% (0.09%) of all of the company's shares and votes.

Option programs

The company has established several share options programs as incentive plans for Bioretec's key personnel, members of the Board of Directors, members of the Scientific Advisory Board, the organizer of the share issue, and the former shareholders of the subsidiary Bioretec GmbH (formerly BRI.Tech GmbH) in connection with the completion of its acquisition in 2019.

On 31 December 2022, there were three stock option programs open: Stock options 2018–1, 2019–1, and 2020–1. The stock options are issued free of charge. The shareholder's rights begin when the shares are registered in the Trade Register. The stock option plans that were open in 2022 or were registered in the Trade Register in 2022 are presented in the table below.

Open option programs:

ID	Options	Share subscription price, EUR	Shares to be subscribed ¹	Subscription period	Unexercised options
2018-1A	8,500,000	1.50	566,666	1.1.2019-31.12.2023	8,500,000
2018-1B	8,500,000	1.50	566,666	1.1.2020-31.12.2023	8,500,000
2018-1C	1,500,000	2.50	100,000	1.1.2021-31.12.2023	1,500,000
2018-1D	1,500,000	2.25	100,000	1.1.2022-31.12.2023	1,500,000
2019-1	36,444,250	0.15	2,429,616	20.3.2019-31.12.2029	36,444,250
2020-1A	8,450,000	2.25	563,324	1.1.2022-31.12.2026	8,450,000
2020-1B	9,150,000	3.00	609,998	1.1.2023-31.12.2026	9,150,000
2020-1C	8,400,000	3.75	559,998	1.1.2024-31.12.2026	8,400,000
Total	82,444,250		5,496,268		82,444,250

¹The decision to establish the stock option plans has been made before the reverse split in spring 2021. After the reverse split, one share corresponds to 15 options.

SIGNIFICANT RISKS AND UNCERTAINTIES

Bioretec's Board of Directors is responsible for Bioretec's risk management. The purpose of risk management is to identify, assess and manage risks so that they do not affect the achievement of the company's objectives. The company has a risk management policy, which is confirmed by the Board of Directors. The risk management policy supports the implementation of the strategy and business objectives and ensures business continuity.

The company has identified risks and uncertainties that could affect the company's results and financial position. It is Bioretec's strategy to identify and manage risks continuously.

Bioretec's risks can be divided into:

- Risks related to the operating environment, industry, and regulations
- Risks related to business
- Risks related to product development, manufacturing, and commercialization of products
- Risks related to financing and
- Risks related to equities, shares, and trading of the shares

The company is exposed to various financial risks, such as liquidity, currency, and credit risk. The most important financial risk is the sufficiency of the funding needed to support the group's strategic growth targets. Liquidity risk is continuously monitored by following up on the amount of available funds and customer credits and open accounts payables as well as reviewing the monthly forecasted cash flow. The Board of Directors has continued actions to explore funding opportunities and to secure the adequacy of funding. Currently, the company's funding will not be sufficient for the full year of 2023.

Industry-related risks are mainly associated with target markets which are both highly regulated and conservative and where the introduction of new technologies happens slowly. Risks related to legislation, rules, and regulatory compliance are associated with the Group's industry sector.

The main risk related to the operating environment is the uncertainty caused by geopolitical tensions, which have already increased energy, material, and logistics costs and reduced the security of supply. Also, the increase in the cost of personnel will be experienced as a result of the already partly completed collective bargaining.

SIGNIFICANT EVENTS AFTER THE REVIEW PERIOD

On 3 January 2023, Bioretec announced that the FDA had confirmed receiving the supplement for the market authorization request for the RemeOs™ trauma screw in the United States.

BOARD OF DIRECTORS' DIVIDEND PROPOSAL

The parent company's distributable funds on 31 December 2022 totaled EUR -1,461,983.58. The Board of Directors proposes that no dividend be paid for 2022.

FINANCIAL REPORTING AND ANNUAL GENERAL MEETING IN 2023

Bioretec will publish its Annual Report, including the Financial Statements, for the year 2022 during week 11/2023, at the latest.

Bioretec's Annual General Meeting is planned to be held on 14 April 2023.

Bioretec's Half-year Report for January–June 2023 will be published on 11 August 2023.

The reports will be available immediately after publication on the company's website at <https://bioretec.com/investors/investors-in-english/reports-and-presentations>.

FORWARD-LOOKING STATEMENTS

The report contains certain forward-looking information that reflects Bioretect's current views of future events and financial and operational performance. Words such as "intends", "anticipates", "expects", "can", "plans", "estimates", and similar expressions regarding indications or forecasts of future developments or trends, and which are not based on historical facts, constitute forward-looking information. Forward-looking information is inherently associated with known and unknown risks and uncertainties because it depends on future events and circumstances. Forward-looking information is not a guarantee of future results or developments, and actual results may differ materially from results referred to in forward-looking information. Forward-looking information in the report is only applicable on the date of issue of the report. Bioretect does not commit to publishing updates or revisions of any forward-looking statements as a result of new information, future events or similar circumstances other than those required by applicable legislation.

ACCOUNTING PRINCIPLES

The consolidated financial statements of the Bioretect Group have been prepared in accordance with the Finnish Accounting Act, as well as with the rules of Nasdaq First North Growth Market Finland. Bioretect Oy and Bioretect GmbH (formerly BRI Tech GmbH) form the Bioretect Group.

Accounting principles have not changed during the reporting period. This Financial Statements Bulletin is unaudited. The full-year 2021 figures are audited.

CONSOLIDATED INCOME STATEMENT

EUR 1,000	H2 2022	H2 2021	Change, %	FY 2022	FY 2021	Change, %
REVENUE	1,520	956	58.9%	2,942	2,003	46.9%
Changes in stocks (FG and WIP)	89	-134		120	-122	-
Other operating income	0	1	-100.0%	4	1	360.5%
Total materials and services	-488	-225	117.0%	-927	-506	83.2%
Total personnel expenses	-1,205	-1,146	5.2%	-2,353	-2,186	7.6%
Total depreciation and amortization	-90	-98	-8.1%	-180	-169	6.3%
Other operating expenses	-832	-793	5.0%	-1,898	-1,687	12.5%
OPERATING PROFIT (LOSS)	-1,006	-1,438	-30.0%	-2,292	-2,666	-14.0%
Net financial expenses	-42	-1,787	-97.7%	-124	-3,350	-96.3%
Profit (loss) before taxes	-1,048	-3,226	-67.5%	-2,415	-6,016	-59.9%
Income taxes	-1	0		-1	-1	0.0%
PROFIT (LOSS) FOR THE PERIOD	-1,049	-3,226	-67.5%	-2,416	-6,017	-59.8%

CONSOLIDATED BALANCE SHEET

EUR 1,000	31 Dec 2022	31 Dec 2021	Change, %
ASSETS			
NON-CURRENT ASSETS			
Intangible assets	427	287	49.1%
Tangible assets	501	571	-12.3%
CURRENT ASSETS			
Total inventories	777	640	21.4%
Short-term debtors	559	461	21.2%
Cash and cash equivalents	1,223	6,621	-81.5%
TOTAL ASSETS	3,488	8,580	-59.4%
EQUITY AND LIABILITIES			
EQUITY			
Restricted share capital	3 749	3,749	0.0%
Other reserves (reserve for unrestricted equity)	9,603	9,603	0.0%
Retained earnings (loss)	-9,015	-2,998	200.7%
Profit (loss) for the period	-2,416	-6,017	-59.8%
LIABILITIES			
Long-term creditors	703	22	3,073.0%
Short-term creditors	864	4,221	-79.5%
TOTAL EQUITY AND LIABILITIES	3,488	8,580	-59.4%

STATEMENT OF CHANGES IN EQUITY

EUR 1,000	H2 2022	H2 2021	Change, %	FY 2022	FY 2021	Change, %
Share capital at the beginning of the period	3,749	3,749	0.0%	3,749	3,749	0.0%
Restricted equity total at the end of the period	3,749	3,749	0.0%	3,749	3,749	0.0%
Share issues at the beginning of the period	0	7,204		0	610	
Period changes	0	-7,204		0	-610	
Share issues at the end of the period	0	0		0	0	
Reserve for invested unrestricted equity at the beginning of the period	9,603	659	1,357.2%	9,603	0	
Period changes	0	8,944		0	9,603	
Reserve for invested unrestricted equity at the end of the period	9,603	9,603	0.0%	9,603	9,603	0.0%
Retained earnings at the beginning of the period	-9,015	-2,998	200.7%	-9,015	-2,998	200.7%
Retained earnings at the end of the period	-10,382	-5,789	-79.3%	-9,015	-2,998	200.7%
Result of the period	-1,049	-3,226	-67.5%	-2,416	-6,017	-59.8%
TOTAL EQUITY	1,921	4,337	-55.7%	1,921	4,337	-55.7%

FINANCIAL POSITION AND CASH FLOW

EUR 1,000	H2 2022	H2 2021	Change, %	FY 2022	FY 2021	Change, %
CASH FLOW FROM OPERATING ACTIVITIES						
Cash flow before changes in working capital	-916	-1,340	-31.6%	-2,112	-2,497	-15.4%
Change in working capital	-112	197		-245	114	
Net financial expenses and taxes paid	-1	-2	-28.9%	-2	-5	-48.0%
CASH FLOW FROM OPERATING ACTIVITIES	-1,030	-1,144	-10.0%	-2,360	-2,387	-1.1%
CASH FLOW FROM INVESTMENTS						
Investments in tangible and intangible assets	-244	-254	-3.9%	-260	-393	-33.7%
CASH FLOW FROM INVESTMENTS	-244	-254	-3.9%	-260	-393	-33.7%
CASH FLOW FROM FINANCING						
Paid share issues	0	8,940		0	8,993	
Change in short- and long-term financing	-696	-38	1,753.0%	-1,264	-75	1,585.9%
Paid other financial expenses	-654	-1,747	-62.6%	-1,514	-1,790	-15.4%
CASH FLOW FROM FINANCING	-1,350	7,155		-2,778	7,128	%
Change in liquid assets (+/-)	-2,624	5,756		-5,398	4,348	%
Cash and cash equivalents at the beginning of the period	3,847	865	344.8%	6,621	2,273	191.3%
Cash and cash equivalents at the end of the period	1,223	6,621	-81.5%	1,223	6,621	-81.5%

DEFINITIONS OF KEY FIGURES

Key figure	Calculation formula
Sales margin	Revenue + other operating income - change in inventories - materials and services
Sales margin, %	(Sales margin / Revenue) x 100
EBITDA	Revenue + other operating income – change in inventories – materials and services -personnel expenses – other operating expenses
EBIT	Revenue + other operating income – change in inventories – materials and services -personnel expenses – other operating expenses – depreciation and amortization
Net profit (loss)	Revenue + other operating income – change in inventories – materials and services -personnel expenses – other operating expenses – depreciation and amortization – net financial expenses – income taxes
R&D spend on total costs, %	Research and development expenses / (personnel expenses + depreciation + other operating expenses) x 100
Equity ratio, %	Total equity at the end of the period / (total liabilities at the end of the period- advances received at the end of the period) x 100
Cash and cash equivalents	Cash and cash equivalents including money market deposits at the end of the period
Earnings per share (undiluted)	Profit (loss) of the period/shares outstanding at the end of the period
Earnings per share (diluted)	Profit (loss) of the period / (shares + convertible securities outstanding at the end of the period)

Tampere, 17 February 2023

Board of Directors

Bioretec Ltd

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Information about Bioretec

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.

Bioretec is developing the new RemeOs™ product line based on a magnesium alloy and hybrid composite, introducing a new generation of strong bioresorbable materials for enhanced surgical outcomes. 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 value for patients through efficient healthcare. The first RemeOs™ product market authorizations are expected in the U.S. during April 2023 and in Europe during 2023. 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. www.bioretec.com.