

Half-year report 2024 (unaudited)

RemeOsTM trauma screw controlled launch in the U.S. yielded expected positive clinical results

APRIL-JUNE 2024 IN BRIEF

- Net sales increased by 68% and amounted to EUR 1,379 thousand (4-6/2023: EUR 820 thousand).
- Sales margin (excl. other income) was EUR 1,033 (609) thousand, or 74.9% (74.3%) of net sales.
- Profit (loss) for the reporting period was EUR -787 (-1,518) thousand. The comparison period included the cost of financing arrangement amounting to EUR 795 thousand.

JANUARY-JUNE 2024 IN BRIEF

- Net sales amounted to EUR 2,061 thousand (1-6/2023: EUR 1,891 thousand).
- Sales margin (excl. other income) was EUR 1,451 (1,327) thousand or 70.4% (70.2%) of net sales. The sales margin in January-June 2024 includes other income of EUR 72 (0) thousand accrued relating to a Business Finland grant.
- Profit (loss) for the reporting period was EUR -1,884 (-2,075) thousand.
- Earnings per share (undiluted) were EUR -0.09 (-0.11).

This half-year report is unaudited. Figures for the second quarter have not previously been published.

KEY FIGURES

EUR 1,000 unless otherwise noted	4-6/2024	4-6/2023	Change, %	1-6/2024	1-6/2023	Change, %	1-12/2023
Net sales	1,379	820	68.3%	2,061	1,891	9.0%	3,906
Sales margin	1,045	609	71.6%	1,523	1,327	14.8%	2,810
Sales margin (excl. other income)	1,033	609	69.8%	1,451	1,327	9.4%	2,728
Sales margin, % of net sales	75.7	74.3		73.9%	70.2%		71.9%
Sales margin% (excl. other income)	74.9	74.3		70.4%	70.2%		69.8%
EBITDA	-752	-639	17.8%	-1,864	-1,130	65.0%	-2,833
EBIT	-782	-690	13.4%	-1,921	-1,233	55.8%	-3,034
Profit/-loss for the period (+/-)	-787	-1,518	-48.2%	-1,884	-2,075	-9.2%	-3,789
R&D spend on total costs, %	23.9%	33.5%		24.8%	29.2%		25.6%
Equity ratio, %	77.9%	85.6%		77.9%	85.6%		77.3%
Cash and cash equivalents at the end of the period	3,947	9,196	-57.1%	3,947	9,196	-57.1%	6,910
Earnings per share (undiluted)	-0.04	-0.07		-0.09	-0.11		-0.19
Earnings per share (diluted)	-0.04	-0.06		-0.08	-0.09		-0.15
Shares at end of period (undiluted)	20,336,858	19,136,858		20,336,858	19,136,858		19,536,858
Shares at end of period (diluted)	24,908,133	23,908,133		24,908,133	23,908,133		24,908,133
Personnel at end of period	43	30	43.3%	43	30	43.3%	37

KEY EVENTS IN APRIL - JUNE 2024

- In May, Alan Donze was appointed Bioretec's CEO.
- In June, Frank Sarcone was appointed as Vice President of Sales for the US and a member of the Management team.
- Also in June, Bioretec communicated positive clinical outcomes from the controlled launch of RemeOs™ trauma screw.
- European market authorization application for the RemeOsTM trauma screw returned from expert panel evaluation in June and the market authorization is expected later compared to earlier estimate (Q2/2024).

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CEO'S COMMENTS

Excited to take the lead at Bioretec

Bioretec's controlled launch plan was designed to systematically gather surgeon feedback and clinical evidence from selected hospitals. In the first half of the year, we received invaluable positive feedback from surgeons regarding the user experience. More importantly, all treated patients experienced the expected healing outcomes, which will facilitate expansion outside the controlled launch plan centers. Our research and development efforts have been focused on expanding the RemeOsTM product portfolio in the U.S. Notably, the FDA granted another Breakthrough Device designation to Bioretec for the RemeOsTM Spinal Cage, an osteopromotive and absorbable cervical spine interbody device made from patented hybrid composite. After my first weeks as the CEO of Bioretec, I am very excited about the opportunities presented by the RemeOsTM product line, which we are actively expanding.

The controlled launch of the RemeOs™ trauma screw has proceeded as expected. All surgical procedures using RemeOs™ technology in the U.S. have been successful, with all cases achieving fracture healing and no adverse events or complications during the follow-up period. With these expected positive outcomes and feedback from surgeons, we are preparing to enter the next phase of the launch in the U.S. This phase will involve expanding the distribution of the trauma screw from a selected group of hospitals to a broader network. With the recent appointment of a new VP of Sales in the U.S., we have bolstered our management team, positioning us to enhance our commercialization efforts in this market.

The strong global performance of the Activa product line marked Bioretec's second quarter of 2024. Net sales grew by 68% from the first quarter due in part to a planned shutdown for new machinery investments resulting in an expected backlog. Sales in the United States saw significant growth, while in Europe, the increase was primarily driven by robust demand from new distributors. However, net sales in the rest of the world declined due to a slight decrease in demand in China, where governmental volume-based procurement initiatives and other changes affected orders. Our sales margin remained consistent with the previous year, ending at 70.4% (70.2%). As part of our strategic implementation and increased recruitment efforts, operating expenses rose. We hired a sales leader in Germany and Austria in the first half of the year and will initiate direct sales in these markets during the second half of the year.

European CE market authorization application for the RemeOsTM trauma screw is progressing, although the process has been extended beyond the prior estimate. The Expert panel review was completed during the second quarter and our application has now returned to the Notified Body for the final steps of the market approval process. The anticipated European market authorization will provide substantial ability to gather real-world evidence of a variety of indications, which will support indication expansions also in the U.S. In other respects, we saw good development with our R&D efforts. I am especially excited about the unprecedented RemeOsTM Spinal Interbody Cage implant, which recently received the FDA Breakthrough Device Designation in the U.S. market. We will be evaluating our resource needs required for bringing it to the market, together with the other RemeOsTM products in the pipeline.

As we focused on ramping up our production capacity in the first half of the year, we anticipate that our net sales will be more robust in the second half. Expanding production capacity and investing in U.S. market development are crucial components of building our growth platform. We continue with our efforts to introduce more RemeOsTM products to the market incrementally through the US FDA process.

Alan Donze, CEO



SALES AND MARKETING

Moving to the next phase with RemeOs™ in the US

In January-June 2024, Bioretec's net sales grew by 9%, almost double the average market growth of 5%, showing the increasing demand of Bioretec products. Strong growth in the U.S. along with solid demand from new European distributors significantly increased Activa sales. Along with the RemeOs™ controlled launch, we continue to increase Activa sales covering both pediatric and adult patient populations offering a variety of products in historically proven applications.

In April–June 2024, Bioretec's net sales amounted to EUR 1,379 (820) thousand, and in January–June, EUR 2,061 (1,891) thousand. Despite the temporary investment driven shutdown in the first quarter, the first half of the year ended with growth of 9%. In the U.S., net sales ended with 68% growth for the second quarter, and YTD net sales grew 112%.

Sales by geographical area

In January–June 2024, 25% (20%) of net sales came from Europe, 19% (10%) from the U.S., and 57% (70%) from the rest of the world. Net sales in the United States increased significantly. Sales of the new RemeOsTM screw in the first half of 2024 amounted only to EUR 11 thousand as the distributor works through initial stocking inventory from the previous year. However, increasing interest in the Activa product family led to strong sales growth of 98% for the period. In Europe, the growth was mainly driven by strong demand from new distributors appointed in the previous year. Net sales in the rest of the world decreased by 12%. This was due to slightly lower demand in China, as the local market was impacted by the continuing transition towards volume-based procurement (VBP). VBP-related price cuts may also impact Bioretec products during the coming periods.

EUR 1,000	1–6/2024	1-6/2023	Change, %	1–12/2023
Europe	508	374	35.9%	621
U.S.	383	181	112.3%	853
Rest of the world	1,170	1,336	-12.4%	2 432
TOTAL	2,061	1,891	9.0%	3,906

Market development

Bioretec operates in the global orthopedic market, which grew well above historical rates to an estimated USD 59.0 billion in 2023, up from USD 55.5 billion in 2022, a 6.3% increase due to the resumption of surgeries postponed during the pandemic. In 2023, the overall market was about three basis points higher than its historical growth rate, and the tailwind is expected to continue modestly through 2024. The market landscape is extremely concentrated; in 2024, it is estimated that more than 65% of all orthopedic sales are generated by just seven major companies, each with over USD 2 billion in annual sales.

Bioretec's strategic emphasis is on orthopedic trauma products, valued at around USD 8.5 billion in 2023, representing 14% of the global market. Through 2027, the trauma market is projected to grow up to 10.2 billion with a CAGR of 5.0%. One of the current key focus areas for Bioretec is the foot and ankle segment, which stands out as a dynamic and growing market, attracting a wide range of players from industry leaders to innovative disruptors. Given the segment's vast array of treatments and products, it forms a key focus area in Bioretec's short and medium-term product pipeline. Industry forecasts project a robust 7% annual growth rate for the foot and ankle market from 2021 to 2025, potentially reaching a total market value of USD 5.6 billion in 2025. Bioretec is well-positioned to leverage this potential and capitalize on the opportunities in the evolving orthopedic landscape.

During 2023, the largest geographic market in orthopedic trauma products was the United States, with a 67% share, and is currently the main highest priority market for Bioretec. In Europe, the Medical Device Regulation is seen as a regulatory hurdle creating significant expense for companies opting to stay in that market area. Europe, however, continues as one of Bioretec's target areas by supporting the RemeOsTM indication expansion into the U.S. with real world evidence on wide variety of indications. China, despite the recent offsetting impacts of VBP (volume-based procurement) will remain strategically an important growth market for major orthopedic companies, as it is estimated to become the largest market (per volume) in the world in coming years.

In the long term, the orthopedic trauma market is poised for continued growth, driven by favorable demographics toward longer life expectancy but increased incidence 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.

¹Source for market forecasts: Orthoworld: The Orthopedic Industry Annual Report published June 2024.



RESEARCH AND DEVELOPMENT

R&D focus continues to deliver groundbreaking results

Bioretec's research and development has concentrated its efforts over the past few months on supporting commercial activities in the U.S.:

- Gathering real-world evidence from completed surgeries in collaboration with operating surgeons,
- Working on expanding RemeOs[™] trauma screw product group,
- Achieving Breakthrough Device Designation for our groundbreaking absorbable and osteopromotive cervical interbody device i.e., RemeOs[™] Spinal Cage.

Product development in the new RemeOs™ product family

The next phase in the development of RemeOsTM trauma screws is the expansion of product group registrations and indications in the U.S. Recently, our R&D efforts have focused on collaborating with the FDA to achieve this goal. The ongoing U.S. and forthcoming EU post-market clinical real-world evidence will play a crucial role in shaping the future roadmap for indication expansions.

The next product in the pipeline for commercialization is the RemeOs™ DrillPin (2025), which has recently received ethical committee approval for the first clinical trial. The initial indication for these DrillPins is hammertoe correction. The RemeOs™ DrillPin offers foot and ankle surgeons similar benefits as the RemeOs™ trauma screws, being both osteopromotive and absorbable. Additionally, they provide ease of use by being self-drilling and can be cut to the desired length, making them versatile in various patient populations. Hammertoe affects around 60 million Americans, with more than half a million surgical corrections performed annually. The upcoming first-in-human clinical trial for the RemeOs™ DrillPins in Austria marks a significant milestone in the product's development. As a pre-market clinical trial, it requires ethical committee approval and additional approval from the national competent authority. This trial is essential to demonstrate the safety and efficacy of the RemeOs™ DrillPins, making the product available for surgeons and patients in the future.

Following the FDA granting Breakthrough Device designation for the RemeOs™ Spinal Interbody Cage for Anterior Interbody Cervical Fusion (AICF), we have initiated the planning of a research and development roadmap to bring this innovative product to market. The Breakthrough Device designation is awarded to devices that meet specific criteria, including providing more effective treatment of irreversibly debilitating conditions and offering significant advantages over existing alternatives. This designation includes benefits such as priority review, intensive FDA guidance, and the opportunity for accelerated review, ensuring that patients and healthcare providers have timely access to these groundbreaking devices. The RemeOs™ Spinal Interbody Cage is an innovative medical device engineered from a multifunctional, MRI-compatible, absorbable hybrid composite. This device will address the limitations of traditional non-degradable implants by minimizing complications and enhancing patient quality of life. It features an osteopromotive core made of a RemeOs™ Mg-Ca-Zn alloy and an osteostimulative shell composed of a bioactive composite. Designed to promote new bone formation and maintain mechanical stability, the RemeOs™ Spinal Interbody Cage supports the fusion process until the bone achieves structural integrity. This advanced device will represent a significant advancement in spinal therapies.

Product development in the current Activa product family

The Post-Market Clinical Follow-up (PMCF) multicenter study on the biodegradable Activa IM-Nail™ for pediatric forearm fractures is nearing completion of patient enrollment targets. Participating Surgeons recently published (*J. Clin. Med.* 2024, 13(14), 4036; https://doi.org/10.3390/jcm13144036) in the Journal of Clinical Medicine results from the surgeries they conducted as part of the PMCF study and concluded that Activa IM-Nail™ are effective for pediatric forearm fractures, providing stable bone healing with high patient satisfaction.

A clinical trial of the Activa IM-NailTM for treating pediatric distal radius fractures at a Level 1 pediatric trauma center has been completed while reporting is ongoing. This study compared the Activa IM-NailTM with the traditional method of percutaneous pinning using metallic Kirschner wires. The results, presented at the joint Congress of European and North American Pediatric Societies (EPOSNA) in May 2024, included 143 patients under 14 years old with unstable distal radial or forearm metaphyseal fractures and open growth plates. The study demonstrated that the Activa IM-NailTM group experienced significantly fewer minor complications. Additionally, no patients required secondary interventions for implant removal, unlike the K-wire group where removal was necessary for all children. The Activa IM-NailTM group also had fewer unplanned medical check-ups in the first six weeks. Following the completion of this trial and the reporting of results, the next steps will involve initiating the registration process for the Activa IM-NailTM in the U.S. market and exploring the expansion of its indications in Europe.



FINANCIAL REVIEW

Group financial development

NET SALES, PROFITABILITY, AND FINANCIAL PERFORMANCE

Net sales and sales margin

In April–June 2024, Bioretec Group's net sales grew 68.3% yearly, amounting to EUR 1,379 (820) thousand. Net sales for January–June 2024 amounted to EUR 2,061 (1,891) thousand. Growth was mainly due to increased demand for Activa product family in the U.S. and Europe.

Sales margin (excl. other income) in April–June 2024 amounted to EUR 1.033 (609) thousand or 74.9% (74.3%) of net sales. For January–June 2024, the sales margin (excl. other income) was EUR 1,451 (1,327) thousand, and the sales margin (excl. other income) was well in line with previous year ending to 70.4% (70.2%).

Operating expenses

In April–June 2024, Bioretec Group's total operating expenses were EUR 1,827 (1,299) thousand. In January–June 2024, operating expenses grew 34%, amounting to EUR 3,444 (2,560) thousand. The increase is largely due to a growing headcount (+43% since June 2023) and ongoing efforts in commercialization in the U.S. and product development.

The Group's R&D expenses in January–June 2024 grew 14%, totaling to EUR 854 (748) thousand. The growth was related to the various ongoing development projects and additional headcount.

EBITDA and net profit (loss) for the period

Bioretec Group's EBITDA in April-June 2024 amounted to EUR -752 (-639) thousand. EBITDA for January–June amounted to EUR -1,864 (-1,130) thousand. Net loss for January–June 2024 was EUR -1,884 (-2,075) thousand. The comparison period included the cost of financing arrangement amounting to EUR 795 thousand.

FINANCIAL POSITION AND CASH FLOWS

On 30 June 2024, the Group's equity ratio was 78% (86%), and the Group's total liabilities were EUR 1,847 (1,669) thousand. Interest-bearing liabilities amounted to EUR 721 (708) thousand, including EUR 484 (421) thousand of long-term liabilities.

At the end of the reporting period, the Group had EUR 3,947 (9,196) thousand of cash and cash equivalents and money market deposits.

In January–June 2024, cash flow from operating activities totaled EUR -2,259 (-1,190) thousand.

Cash flow from financing activities in January-June 2024 was EUR -247 (9,237) thousand. Capital loan of EUR 276 thousand and related accrued interest amounting to EUR 41 thousand were paid during the period. The cash flow for the comparison period included funds of EUR 10 million from the stock issuance completed at the end of April 2023. The cost of the arrangement, EUR 795 thousand, is included under the cash flow from financing activities.

In January–June 2024, the Group's capital expenditure totaled EUR 457 (73) thousand. Investments during the financial period included new production machinery, production facility modifications, costs on IPRs and market authorization processes, and costs capitalized on the new ERP system.

FINANCIAL TARGETS

In April 2023, after having received market authorization in the U.S. for the first product in the RemeOsTM product family, Bioretec updated its product pipeline and related commercialization strategy, and consequently updated its financial targets as follows:

- to reach net sales of EUR 62 million by the end of the year 2027 and
- to reach positive cash flow from operating activities by the end of the year 2026.

PERSONNEL AND MANAGEMENT

At the end of June 2024, Bioretec had 43 (30) employees. The average number of employees from 1 January to 30 June 2024 was 39 (29). Salaries and other personnel expenses in January–June 2024 totaled EUR 1,690 (1,221) thousand.

Alan Donze was appointed the CEO and Timo Lehtonen the CTO of Bioretec as of 20 May 2024. Frank Sarcone was appointed as Vice President of Sales for the US and a member of the Management Team as of 17 June 2024. On 30 June 2024, the members of Bioretec's Management Team were Alan Donze (Chief Executive Officer), Timo Lehtonen (Chief Technology Officer) Johanna Salko (Chief Financial Officer), Minna Ahlstedt-Soini (Production



Director), Rami Ojala (Sales and Marketing Director), Mari Ruotsalainen (Director of QA & RA), Esa Hallinen (Director of Operations) and Frank Sarcone (VP of US sales).

BOARD OF DIRECTORS

On 30 June 2024, Bioretec's Board of Directors had five members: Tomi Numminen (Chairman of the Board), Michael Piccirillo, Sarah van Hellenberg Hubar-Fisher, Päivi Malinen and Kustaa Poutiainen.

AUDITOR

Bioretec's auditors are Authorized Public Accountants PricewaterhouseCoopers, with Kalle Laaksonen, Authorized Public Accountant, as the responsible auditor.

ANNUAL GENERAL MEETING AND BOARD AUTHORIZATIONS

The Annual General Meeting of Bioretec Ltd was held on 26 April 2024 in Tampere, Finland. The Annual General Meeting approved the financial statements for the financial year 1 January–31 December 2023 and resolved to discharge the members of the Board of Directors and the CEO from liability for the financial period from 1 January–31 December 2023. The Annual General Meeting approved the Board of Directors' proposal not to distribute dividends

The Annual General Meeting resolved that the Board of Directors shall have five members. Tomi Numminen, Michael Piccirillo, Sarah van Hellenberg Hubar-Fisher, Päivi Malinen and Kustaa Poutiainen were re-elected as members of the Board. The term of the Board of Directors will end at the closing of the Annual General Meeting 2025

At its constitutive meeting held after the Annual General Meeting, the Board of Directors elected Tomi Numminen as Chairman of the Board. The Board also resolved to establish an Audit Committee and a Nomination /Remuneration Committee. The members of the Committees were elected as follows:

- Audit Committee: Tomi Numminen (chairperson), Päivi Malinen and Sarah van Hellenberg Hubar-Fisher
- Nomination/Remuneration Committee: P\u00e4ivi Malinen (chairperson), Michael Piccirillo and Kustaa Poutiainen

The Annual General Meeting resolved that the Chairman of the Board will be paid EUR 10,000 per month and the members of the Board EUR 1,500 per month. Reasonable travel expenses of the members of the Board of Directors shall be reimbursed in accordance with the maximum amount of the respective travel allowance base approved by the Tax Administration.

The Annual General Meeting resolved that the company may enter into a consultancy agreement with Valugen GmbH for the services of Michael Piccirillo in connection with establishing the company's Scientific Advisory Board and with creating key opinion leader connections. The consulting fee payable pursuant to such agreement shall not exceed EUR 3,000 per month.

The Annual General Meeting elected audit firm PricewaterhouseCoopers Oy as the auditor of the company until the closing of the 2025 Annual General Meeting. Audit firm PricewaterhouseCoopers Oy has notified the company that it will appoint Kalle Laaksonen, 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 authorized 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:

Pursuant to the authorization, up to 3,000,000 shares, including the new shares to be issued based on the special rights can be issued, which on the date of the notice to the Annual General Meeting corresponded approximately to 15 per cent of all the shares in the company.

The shares or special rights entitling to shares can be issued in one or more instalments, either against or without payment. The shares issued pursuant to the authorization may be new shares or shares in the company's possession. The authorization may be used for 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.

Pursuant to 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 was 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 2025. The authorization cancels previous unused share issue authorizations.



Establishment of a Shareholders' Nomination Board and Approval of the Charter

The Annual General Meeting resolved to establish a Shareholders' Nomination Board, responsible for annually preparing and presenting to the Annual General Meeting and, if necessary, to an Extraordinary General Meeting, proposals on the composition (number of the members of the Board of Directors and the nominees) and remuneration of the Board of Directors. In addition, the Nomination Board is responsible for identifying candidates to succeed members of the Board of Directors and preparing principles for diversity for the Board of Directors. The Nomination Board consists of three members. The company's three largest shareholders are each entitled to nominate one member. The Chairman of the Board of Directors of the company serves as an expert in the Nomination Board and will not have a voting right nor be counted in the quorum of the Nomination Board. The Annual General Meeting resolved to approve the Charter of the Shareholders' Nomination Board, which is available on the company's website at https://bioretec.com/agm2024.

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 30 June 2024, Bioretec had a total of 20,336,858 (19,136,858) shares. During the reporting period, the average number of shares was 19,936,858 (16,624,358). The average number of shares (diluted) during the reporting period was 24,908,133 (21,758,130). Bioretec does not hold its shares. The share capital was EUR 3,749 (3,749) thousand.

There were 124 trading days in the review period. A total of 4,396,119 (3,980,556) shares were traded during the period, and the total value of the shares traded was EUR 10,981,141 (10,204,324). The highest price of the share was EUR 2.94 (3.26), and the lowest price was EUR 2.21 (1.40). The volume-weighted average price was EUR 2.50 (2.56), and the closing price at the end of the period was EUR 2.88 (2.49). In accordance with the closing price, the combined market value of the shares was approximately EUR 58.6 (47.6) million.

Shareholders

Bioretec's shares are in the book-entry system maintained by Euroclear Finland, and Euroclear Finland maintains Bioretec's official shareholder register. On 30 June 2024, Bioretec had a total of 4,678 (3,781) registered shareholders, of whom 93% (92%) were private individuals. There were 1,244,482 (739,045) nominee-registered and foreign-owned shares, which was 6% (4%) 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.

On 30 June 2024, the members of Bioretec's Board of Directors owned a total of 2,223,060 (1,212,690) company shares. The CEO did not own any of the company's shares (at the end of June 2023, 0 shares). Other members of the Group's Management Team owned a total of 5,624 (5,624) company shares. Consequently, the company's executive management held 11.0% (6.34%) 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 in connection with the completion of its acquisition in 2019.

On 30 June 2024, there were four stock option programs open: stock options 2018–1, 2019–1, 2020–1 and 2023–1. 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 the first half of 2024 or that were registered in the Trade Register in the first half of 2024 are presented in the table below.

Open option programs:

Program ID	Nr of options	Share subscription price, EUR	Nr of shares to be subscribed ¹	Subscription period	Nr of unexercised options ²	subscribed based on remaining unexercised options ¹
2018-1A	8,500,000	1.50	566,666	1.1.2019-31.12.2026	8,125,000	541,667
2018-1B	8,500,000	1.50	566,666	1.1.2020-31.12.2026	8,500,000	566,667
2018-1C	1,500,000	2.25	100,000	1.1.2021-31.12.2026	1,500,000	100,000
2018-1D	1,500,000	2.25	100,000	1.1.2022-31.12.2026	1,500,000	100,000
2019-1	36,444,250	0.15	2,429,616	20.3.2019-31.12.2029	18,444,250	1,229,616
2020-1A	8,450,000	2.25	563,324	1.1.2022-31.12.2026	5,650,000	376,662
2020-1B	9,150,000	3.00	609,998	1.1.2023-31.12.2026	5,300,000	353,332
2020-1C	8,400,000	3.75	559,998	1.1.2024-31.12.2026	4,550,000	303,332
2023-1	1,000,000	2.84	1,000,000	21.10.2024-31.12.2029 ³	1,000,000	1,000,000
Total	83,444,250		6,496,268		54,569,250	4,571,275

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

Nr of charge to be



² The remaining number of unexercised options has been deducted from the number of already registered share subscriptions. Additionally, those options that have remained unallocated from 1 January 2023 onwards have been deducted from the amount of the remaining option, as the board authorization concerning option program 2020-1 ended on 31 December 2022

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

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, customer credits, and open accounts payables as well as reviewing the monthly forecasted cash flow.

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. One of the main risks related to the operating environment is the uncertainty caused by geopolitical tensions. Those have already increased energy, material, and logistics costs, reduced the security of supply, and reduced sales.

SIGNIFICANT EVENTS AFTER THE REVIEW PERIOD

No significant events to report.

FINANCIAL REPORTING IN 2024

In 2024, Bioretec will publish the following financial reports:

• business review for January–September 2024 on Thursday 14 November 2024

The releases will be available online at Bioretec Ltd'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 Bioretec'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. Bioretec 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

Bioretec Group's half-year report has been prepared in accordance with the Finnish Accounting Act, as well as with the rules of Nasdaq First North Growth Market Finland. Bioretec Oy, Bioretec GmbH and Bioretec Inc. form the Bioretec Group.

Accounting principles have not changed during the reporting period. This half-year report is unaudited. The full-year 2023 figures are audited.

December 2022.

3 As of 21 October 2024, 25% of the option rights given to the option right holder can be subscribed. As of 30 November 2024, shares can be subscribed in monthly installments of 1/36th of the remaining 75% of the option rights given to the option right holder until 31 December 2029.

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CONSOLIDATED INCOME STATEMENT

UR 1,000	1–6/2024	1-6/2023	Muutos, %	1-12/2023
REVENUE	2,061	1,891	9.0%	3,906
Changes in stocks (FG and WIP)	178	48	273.4%	-8
Other operating income	71	0	-	82
Total materials and services	-788	-612	28.9%	-1,170
Total personnel expenses	-1,690	-1,221	38.5%	-2,850
Total depreciation and amortization	-57	-103	-44.9%	-201
Other operating expenses	-1,696	-1,236	37.3%	-2,793
OPERATING PROFIT (LOSS)	-1,921	-1,233	55.8%	-3,034
Net financial expenses	38	-842	-104.5%	-754
Profit (loss) before taxes	-1,883	-2,074	-9.2%	-3,788
Income taxes	-1	-1	0.0%	-1
PROFIT (LOSS) FOR THE PERIOD	-1,884	-2,075	-9.2%	-3,789

CONSOLIDATED BALANCE SHEET

EUR 1,000	30 Jun 2024	30 Jun 2023	Change, %	31 Dec 2023
ASSETS				
NON-CURRENT ASSETS				
Intangible assets	581	417	39.6%	484
Tangible assets	1,088	477	128.1%	789
CURRENT ASSETS				
Total inventories	1,136	847	34.1%	842
Short-term debtors	1,560	616	153.4%	1,632
Cash and cash equivalents	3,947	9,196	-57.1%	6,910
TOTAL ASSETS	8,313	11,553	-28.0%	10,657
EQUITY AND LIABILITIES				
EQUITY				
Restricted share capital	3,749	3,749	0.0%	3,749
Other reserves (reserve for unrestricted equity)	19,821	19.641	0.9%	19,701
Retained earnings (loss)	-15,219	-11.431	33.1%	-11,431
Profit (loss) for the period	-1,884	-2.075	-9.2%	-3,789
LIABILITIES				
Long-term creditors	484	421	14.8%	671
Short-term creditors	1,364	1,248	9.3%	1,756
TOTAL EQUITY AND LIABILITIES	8,313	11,553	-28.0%	10,657

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STATEMENT OF CHANGES IN EQUITY

EUR 1,000	1-6/2024	1-6/2023	Change, %	1-12/2023
Share capital at the beginning of the period	3,749	3,749	0.0%	3,749
Restricted equity total at the end of the period	3,749	3,749	0.0%	3,749
Reserve for invested unrestricted equity at the beginning of the period	19,701	9,603	105.1%	9,603
Period changes	120	10,038	-98.8%	10,098
Reserve for invested unrestricted equity at the end of the period	19,821	19,641	0.9%	19,701
Retained earnings at the beginning of the period	-15,219	-11,431	33.1%	-11,431
Retained earnings at the end of the period	-15,219	-11,431	33.1%	-11,431
Result of the period	-1,884	-2,075	-9.2%	-3,789
TOTAL EQUITY	6,466	9,884	-34.6%	8,230

FINANCIAL POSITION AND CASH FLOW

EUR 1,000	1-6/2024	1-6/2023	Change, %	1-12/2023
CASH FLOW FROM OPERATING ACTIVITIES				
Cash flow before changes in working capital	-1,864	-1,130	65.0%	-2,833
Change in working capital	-387	-60	548.2%	-598
Net financial expenses and taxes paid	-8	-1	762.1%	-6
CASH FLOW FROM OPERATING ACTIVITIES	-2,259	-1,190	89.8%	-3,437
CASH FLOW FROM INVESTMENTS				
Investments in tangible and intangible assets	-457	-73	523.5%	-161
CASH FLOW FROM INVESTMENTS	-457	-73	523.5%	-161
CASH FLOW FROM FINANCING				
Paid share issues	120	10,037	-98.8%	10,098
Change in short- and long-term financing	-325	-5	6,159.6%	-37
Paid other financial expenses	-41	-795	-94.8%	-775
CASH FLOW FROM FINANCING	-246	9,237	-102.7%	9,286
Change in liquid assets (+/-)	-2,963	7,973	-137.2%	5,688
Cash and cash equivalents at the beginning of the period	6,910	1,223		1,223
Cash and cash equivalents at the end of the period	3,947	9,196		6,911



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) for 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, 15 August 2024

Board of Directors

Bioretec Ltd

For additional information about the report:

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Information about Bioretec

Bioretec is a globally operating Finnish medical device company that continues to pioneer the application of biodegradable 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 RemeOsTM product line based on a magnesium alloy and hybrid composite, introducing a new generation of strong biodegradable materials for enhanced surgical outcomes. The RemeOsTM implants are absorbed 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 RemeOsTM product market authorization has been received in the U.S. in March 2023, and in Europe, the CE-mark approval process is currently on-going. Bioretec is positioning itself to enter the addressable USD 7 billion global orthopedic trauma market and become a game changer in surgical bone fracture treatment.

Better healing – Better life. <u>www.bioretec.com</u>