

Bioretec Ltd

Board of Directors' Report and Financial Statements 2023



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Accounting period: 1 January–31 December 2023

Financial statements must be retained until 31 December 2033.

Financial statements have been prepared by Accountor Services Oy.



Board of Directors' Report for the financial year 2023

Bioretec in brief

Bioretec is a globally operating Finnish medical device company that continues to pioneer the application of biodegradable¹ orthopedic implants. The company has unique expertise combining materials engineering and biochemistry in active implants that promote bone growth and accelerate fracture healing after orthopedic surgery. The products developed and manufactured by Bioretec are sold worldwide in approximately 40 countries.

The majority of Bioretec's net sales come from exports. In 2023, 1% of net sales came from Finland and 99% from other countries. The company's end customers include public and private hospitals and hospital chains. Bioretec's products are sold through the company's distributor network.

Bioretec has two product families. The company's new RemeOs™ product line is based either on magnesium alloy or magnesium alloy-based hybrid composite, introducing a new generation of strong biodegradable materials. The first magnesium alloy product, the RemeOs™ trauma screw, was granted U.S. market authorization in March 2023, and the first U.S. deliveries of the trauma screws were started in the second half of 2023. Other RemeOs™ family products still in the development process are the DrillPin, IM-Nail, and spinal cage, and the latest additions are the RemeOs™ staples and RemeOs™ plates. The EU market authorization for the RemeOs™ screw is anticipated in the second quarter of 2024. Bioretec's Activa product portfolio consists of biodegradable biopolymer products available for pediatric, trauma, and sports surgery.

Bioretec headquarters and its manufacturing operation is located in Tampere, Finland. At the end of 2023, the company had 37 employees, of which 36 were employed in Finland. Bioretec's shares are traded on the Nasdaq First North Growth Market Finland marketplace. At the end of 2023, Bioretec Group consisted of the parent company Bioretec Ltd (domicile: Finland) and its wholly owned subsidiaries Bioretec GmbH (domiciled in Austria) and Bioretec Inc. (domiciled in the United States).

The company complies with the Finnish Accounting Standards (FAS) in its preparation of consolidated financial statements. In addition, Bioretec complies in its decision-making and corporate governance, for example, with the Finnish Limited Liability Companies Act, securities market legislation, its Articles of Association, and the Nasdaq First North rules. The company also complies with its ethical code of conduct.

Significant events during the review period

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

¹ In this release the term (bio)degradable is interchangeable with (bio)absorbable and (bio)resorbable

Consolidated key figures

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

Net sales, profitability and financial performance

NET SALES AND SALES MARGIN

Net sales for the financial period from January to December 2023 amounted to EUR 3,906 (2,942) thousand. In 2023, Bioretec's net sales continued the robust growth trend with year-on-year growth of 33%, driven by the strong performance of Activa products in Asia as well as the total sales growth in the U.S. market. 16% (39%) of net sales came from Europe, 22% (2%) from the U.S., and 62% (59%) from the rest of the world. Net sales in the United States increased significantly, partly due to the first-year sales of EUR 374 thousand of the new RemeOs™ screw, and due to the expanded product offering of the U.S. distributor of Activa products for pediatric markets. Net sales in the rest of the world grew 40%. The growth was mainly driven by China, with a 77% (80%) contribution to the net sales. The growth in China was mainly due to the increased demand caused by the rising number of hospitals using Bioretec's biodegradable products.

Net sales in Europe decreased 45% year on year due to discontinued sales to Russia. Since the start of the war in Ukraine in February 2022, Bioretec has continued only to fulfill its existing contractual sales obligations. Sales in Russia in 2023 were EUR 19 (456) thousand, and contractual obligations in Russia have ended.

EUR 1,000	FY 2023	FY 2022	Change, %
Europe ¹	621	1,138	-45.4%
United States	853	63	1,252.1%
Rest of the world	2,432	1,741	39.7%
Total	3,906	2,942	32.8%

¹ Russia included in Europe.

Sales margin in January–December 2023 grew 31% to EUR 2,810 (2,139) thousand. The sales margin was 72% (73%) of net sales. Sales margin levels were well in line with the previous year.

OPERATING EXPENSES

In January–December 2023, Bioretec Group's total operating expenses grew 32% year on year, amounting to EUR 5,843 (4,430) thousand. The increase was partly due to increased headcount and bonus accruals but also due to U.S. commercialization-related expenses on consulting, legal, marketing, and traveling and additionally due to product development costs of ongoing projects. Additionally, the company invested in the strengthening of the Scientific Advisory Board organization and its operations, which also impacted the costs.

The Group's R&D expenses in 2023 grew 20% year on year and totaled EUR 1,493 (1,245) thousand. The growth was mainly related to the ongoing DrillPin project and the Coating project, partly financed by Business Finland.

EBITDA AND NET PROFIT (LOSS)

Bioretec Group's EBITDA in January–December 2023 amounted to EUR -2,833 (-2,112) thousand. The main reasons for the decrease were mainly the higher costs generated by added headcount and inputs to U.S. commercialization. Net loss for the period was EUR -3,789 (-2,416) thousand. Net loss included the one-off cost of EUR 775 thousand on the financing round arranged in April 2023.

Financial position and cash flows

On 31 December 2023, the Group's equity ratio was 77% (55%) and total liabilities EUR 2,427 (1,566) thousand. Interest-bearing liabilities amounted to EUR 1,046 (713) thousand, including EUR 671 (703) thousand of long-term liabilities. The increase in interest-bearing liabilities was due to the investment of the new CNC machine, which is financed with a three-year agreement.

At the end of the financial period, the Group had EUR 6,910 (1,223) thousand of cash and cash equivalents and money market deposits. The increase in cash was due to the financing round arranged in April 2023.

In January–December 2023, cash flow from operating activities totaled EUR -3,437 (-2,360) thousand. Positive cash flow from financing activities, EUR 9,286 (-2,778) thousand, was due to the financing round arranged in April 2023.

In January–December 2023, the Group's capital expenditure totaled EUR 161 (260) thousand. Investments during the period consisted of costs on IPRs and market authorization processes as well as costs capitalized on the new ERP system currently under implementation.

Research & development

In 2023, Bioretec achieved a historic milestone when the company's RemeOs™ trauma screw gained market authorization from the US Food and Drug Administration (FDA) as the first absorbable metal implant for the US market, a significant leap forward in the company's development work. Following this achievement, Bioretec focused its research and development efforts mainly on expanding the RemeOs™ product range and indications.

PRODUCT DEVELOPMENT IN THE NEW REMEOS™ PRODUCT FAMILY

The RemeOs™ implants are made from biodegradable metal (magnesium-calcium-zinc) (FDA classification is absorbable metal). They are absorbed and replaced by bone and eliminate the need for implant removal surgery while facilitating fracture healing.

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

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

Furthermore, the development of the RemeOs™ DrillPin product group has reached the next phase. During the last quarter of 2023, Bioretec finalized an agreement to conduct a clinical trial at the Medical University Hospital in Graz,

Austria, and started an ethical committee approval process. The purpose of this trial is to validate the safety and effectiveness of the RemeOs™ DrillPin. Designed to cater to a wide patient demographic, the RemeOs™ DrillPin product group is positioned to serve both adult and pediatric patients, addressing a broad spectrum of orthopedic indications.

In addition to the RemeOs™ screws and DrillPins, Bioretec is continuously progressing in the development of other RemeOs™ products in the pipeline. These cutting-edge products are currently undergoing product development, applicability assessment, and research, paving the way for even more transformative solutions in the future. In light of the expanded product portfolio, Bioretec has updated the commercialization timeline for the RemeOs™ DrillPin, now expected in 2025, adjusted from the original forecast of 2024. Bioretec anticipates the launch of RemeOs™ staples in 2026 and RemeOs™ plates in 2027. Furthermore, the introduction of the IM-Nail and the spinal cage, previously estimated for 2026 and 2027, is now anticipated post-2028. Moreover, an ongoing study evaluating different coatings for enhancing future product properties, supported in part by Business Finland, commenced in autumn 2023, highlighting Bioretec's commitment to R&D.

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 Post-Market Clinical Follow-up (PMCF) multicenter study of the biodegradable Activa IM-Nail™, tailored for pediatric use in treating forearm fractures, is progressing as planned across various European countries. The study aims to assess the rate of refracture and ascertain the subjective benefits of Activa IM-Nail™ for patients, parents, and caregivers. By the end of 2023, approximately 81% of the targeted pediatric patients had already undergone treatment, and the project is reaching completion of patient enrollment. Another ongoing clinical trial investigates Activa IM-Nail™ for the treatment of pediatric wrist fractures (Distal Radius) and is conducted as a comparative trial alongside non-biodegradable metallic K-wires. The patient enrollment is completed, and reporting is ongoing. Bioretec expects the results to be published in the forthcoming joint Congress of European and North American Pediatric Societies (EPOSNA) in May 2024.

COLLABORATION WITH LEADING MEDICAL EXPERTS

A key component of Bioretec's development strategy is the invaluable guidance and support from leading experts in the field. In 2023, in line with the evolving product portfolio, Bioretec significantly enhanced its Scientific Advisory Board. This expanded board features a group of surgeons, each a top-tier expert in their respective specialties, including Foot & Ankle, Trauma, Pediatrics, and Spine. The SAB members in orthopedic trauma include Prof. Dr. Klaus Dresing from Germany and Prof. Dr. Fan Liu from China. In foot and ankle surgery, the SAB members are Prof. Dr. Stefan Rammelt from Germany and Dr. Robert Leland from the USA. In pediatric orthopedic trauma, the board members are Prof. Dr. Theddy Slongo from Switzerland and Dr. Verena Schreiber from the USA, and in spine surgery, Prof. Dr. Jeffrey Wang from the USA and Dr. Richard Assaker from France.

Operating environment and 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 6.5% increase due to the resumption of surgeries postponed during the pandemic. In 2023, the 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 concentrated; in 2024, it is estimated that more than 60% of all orthopedic sales are generated by just six major companies, each with over USD 2 billion in annual sales.

Bioretec's strategic emphasis is on orthopedic trauma products, valued at around USD 8.6 billion in 2023, representing 14.5% of the global market. A key focus within this sector 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 66-% share, and it is currently the main target market for Bioretec. In China, the transition to volume-based procurement (VBP), which leads to lower prices for trauma fixation implants, has been advantageous for domestic Chinese manufacturers. Bioretec continues to monitor the VBP progress closely. In Europe, the new, more stringent Medical Device Regulation (MDR) is reshaping the market landscape. This regulation, more rigorous than its predecessor, the Medical Device Directive, has

led to product withdrawals by orthopedic companies, even though the MDR transition deadline has been extended to 2027 or 2028, depending on the device type. Europe as a market remains one of Bioretec's strategic target areas.

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

Significant risks and uncertainties

Bioretec's Board of Directors is responsible for Bioretec's risk management, and its practical implementation is the responsibility of the CEO and other top 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 approved 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 related to 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 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.

Personnel

At the end of 2023, Bioretec had 37 (28) employees. The average number of employees from 1 January to 31 December 2023 was 31 (26). Salaries and other personnel expenses in 2023 totaled EUR 2,850 (2,353) thousand.

Changes in the Management Team

Esa Hallinen was appointed Bioretec's Director of Operations and member of the Management Team as of 7 August 2023. On 31 December 2023, 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), Mari Ruotsalainen (Director of QA & RA) and Esa Hallinen (Director of Operations).

Annual General Meeting and Board authorizations

The Annual General Meeting of Bioretec Ltd was held on 26 May 2023 in Tampere, Finland. The Annual General Meeting approved the financial statements for the financial year 1 January–31 December 2022 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 2022. 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 six members. Tomi Numminen, Michael Piccirillo, Sarah van Hellenberg Hubar-Fisher, Pekka Simula, and Päivi Malinen were re-elected as members of the Board. Additionally, Kustaa Poutiainen was elected as a new member of the Board. The term of the Board of Directors will end at the closing of the Annual General Meeting 2024. At its constitutive meeting held after the Annual General Meeting, the Board of Directors elected Tomi Numminen as Chairman of the Board.

The Annual General Meeting resolved that the Chairman of the Board will be paid EUR 2,500 per month and that the members of the Board will be paid 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 Tomi Numminen for consulting services related to the funding processes of the company and the commercialization of the company's products in the United States. The consultancy fee payable pursuant to such agreement shall not exceed EUR 7,500 per month.

In addition, 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 auditing firm Ernst & Young as the auditor of the company until the closing of the 2024 Annual General Meeting. Auditing firm Ernst & Young has notified the company that it will appoint 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 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:

Under the authorization, up to 5,000,000 shares, including the new shares to be issued based on the special rights can be issued, which at the time of the proposal represents approximately 26 percent of all outstanding company shares.

The shares or special rights entitling to shares can be issued in one or more installments, 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 is 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 2024. The authorization revokes previous unused share issue authorizations.

Amendment of Option Program 2018-1

The Annual General Meeting resolved to extend the subscription period for the shares that the option rights entitle to subscribe for under Option Program 2018-1 until 31 December 2026 as follows:

- With option right 2018-1A: 1 January 2019–31 December 2026
- With option right 2018-1B: 1 January 2020–31 December 2026
- With option right 2018-1C: 1 January 2021–31 December 2026
- With option right 2018-1D: 1 January 2022–31 December 2026

The Annual General Meeting additionally resolved to authorize the Board of Directors to make the required decisions for implementing the resolution of the Annual General Meeting and, in addition, if required, to amend the terms and

conditions of Option Program 2018-1 to reflect the amendments in the Finnish Companies Act in respect of the terms of option rights and other special rights that came into force on 31 January 2023. This authorization was in force until 31 December 2023.

Board of Directors

On 31 December 2023, Bioretec's Board of Directors had six members. The Annual General Meeting held on 26 May 2023 re-elected Tomi Numminen, Michael Piccirillo, Sarah van Hellenberg Hubar-Fischer, Pekka Simula and Päivi Malinen to new terms of office and Kustaa Poutiainen as a new member of the Board of Directors. At its constitutive meeting held after the Annual General Meeting, the Board of Directors elected Tomi Numminen as Chairman of the Board.

The Auditor

Bioretec's Annual General Meeting held on 26 May 2023 auditing firm Ernst & Young as the auditor of the company until the closing of the 2024 Annual General Meeting. Auditing firm Ernst & Young has notified the company that it will appoint Erika Grönlund, Authorized Public Accountant, as the responsible auditor. The auditor will be compensated as reasonably invoiced.

Bioretec's share, share issues and trading on shares

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

On 27 April 2023, Bioretec Ltd completed a private placement of shares to institutional and other experienced investors. In the placing, the company issued a total of 5,000,000 shares, which represented approximately 35.4 percent of the issued shares in the company prior to the placing and approximately 26.1 percent of the issued shares in Bioretec following the placing. The subscription price of the placing shares was EUR 2.00 per share. The placing was based on offers received in an accelerated book building and on the authorization granted to the Board of Directors by the company's Annual General Meeting of 13 April 2022. Bioretec raised gross proceeds of EUR 10 million in the placing.

On 31 December 2023, Bioretec had a total of 19,536,858 (14,111,858) shares. The share capital was EUR 3,749 (3,749) thousand. Bioretec does not hold any equity shares. In 2023, the average number of shares was 16,824,358 (14,111,858). Average number of shares (diluted) in 2023 was 22,258,130 (19,643,566).

There were 251 trading days in the review period. A total of 5,966,391 (2,109,933) shares were traded during this period, and the total value of the shares traded was EUR 15,079,870 (4,379,089). The highest price of the share was EUR 3.75 (3.07), and the lowest price was EUR 1.35 (1.32). The volume-weighted average price was EUR 2.53 (2.31) and the closing price at the end of the period was EUR 2.40 (1.41). In accordance with the closing price, the combined market value of the shares was approximately EUR 46.9 (19.8) 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 31 December 2023, Bioretec had a total of 4,108 (2,519) registered shareholders, of whom 92% (89%) were private households. There were 534,331 (777,143) nominee-registered and foreign-owned shares, which was 2.7% (5.5%) of all shares and total votes. The largest shareholders and shareholders by sector are available on the company's website at www.bioretec.com/investors/investors-in-english/share/shareholders.

On 31 December 2023, the members of Bioretec's Board of Directors owned a total of 1,622,690 (12,690) of the company's shares. The CEO did not own any of the company's shares (at the end of 2022, 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 8.3% (0.13%) of all of the company's shares and votes.

Option programs

The company has established several share option 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 20 October 2023, the company's Board of Directors decided to establish a new option program (Option program 2023-1) as an incentive scheme for the employees, consultants, and members of the Scientific Advisory Board of the company and its subsidiaries. Under Option program 2023-1, a maximum total of 1,000,000 option rights will be issued, and they will entitle their owners to subscribe for a maximum total of 1,000,000 new shares in the company.

On 31 December 2023, four stock option programs were 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. In 2023, 25,000 shares were subscribed under the option program 2018-1A and 400,000 shares under the option program 2019-1. The stock option plans that were open in the end of 2023 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	Nr of shares to be 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	30,444,250	2,029,616
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		66,569,250	5,371,275

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

²The remaining number of unexercised options has been reduced with 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.

³As 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.

Significant events after the review period

On 8 March 2024, Bioretec announced that the company's European market authorization application of the RemeOs™ trauma screw has, according to information received from the Notified Body, progressed to the expert panel stage. The duration of the evaluation is a maximum of 60 days. After this step, the process will return to the Notified Body. Based on the information, the company estimates that the CE mark will be obtained during the second quarter of 2024. The previous estimate was that the market authorization would be granted in the first quarter of 2024.

On 14 March 2024, Bioretec announced that the company's RemeOs™ Spinal Interbody Cage implant had been granted a Breakthrough Device Designation by the FDA. Obtaining the Breakthrough Device Designation status is an important milestone in getting the product launched into the U.S. markets, and Bioretec will therefore evaluate the potential acceleration of RemeOs™ Spinal Interbody Cage product development as well as resource allocation requirements, which might impact the future capital needs of the company.

Estimates of future development

Bioretec's future prospects and profitability are substantially dependent on the company's success in the commercialization of the currently approved magnesium-based RemeOs™ Trauma screws in the U.S. and the go-to-

market success of its upcoming RemeOs™ product pipeline in the United States and Europe. Bionetec has received market authorization for the RemeOs™ screws in the U.S. in March 2023 and is expecting to receive one in the EU during the second quarter of 2024. The company expects moderate growth in the initial phase of the commercialization of the RemeOs™ Trauma screws, as healthcare professionals typically take new products into use gradually to gain their own clinical experience.

Other RemeOs™ products are in different stages of product development, and the target is to commercialize them gradually from 2025 onwards. The company's long-term prospects and profitability will depend on the future success of gathering clinical data and commercialization of these new magnesium and hybrid composite-based products as well as the company's ability to meet its planned schedule.

A significant share of Bionetec's future revenue is expected to come from products still in the development and commercialization phase. The company continues to invest in development to ensure successful market entry of the future products. This product development is estimated to cause operating losses during the next few years. In the near future, the company expects to focus on developing its business by strengthening its growth potential and by financing its growth strategy. The company expects to have a positive operational cash flow by the end of 2026.

Orthopedic trauma is a growing market, and according to forecasts, the market share of biodegradable trauma products is growing and will continue to grow faster than the overall market. The current market trends are aimed at more efficient use of resources and cost control without undermining the clinical outcome. Additionally, at the same time, the world's aging population burdens healthcare and brings new challenges to the global healthcare industry. The biodegradable product innovations developed by Bionetec respond to these market drivers and further significantly increase the demand for biodegradable products.

The Board's proposal for the distribution of parent company profit

On 31 December 2023, the parent company's distributable funds totaled EUR 4,914,201.75. The Board of Directors proposes that the parent company loss of EUR -3,721,314.67 for the financial period from 1 January to 31 December 2023 be credited in the equity as Profit(loss) for previous accounting periods and that no dividend be distributed.

Formulas

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)

Consolidated income statement

EUR	1 January–31 December 2023	1 January–31 December 2022
REVENUE	3,906,174.41	2,941,944.07
Change in stocks of finished goods and work-in-progress increase (+) or reduction (-)	-7,732.85	120,309.08
Other operating income	81,687.03	3,600.00
Materials and services		
Materials, supplies and goods		
Purchases during the accounting period	-1,056,066.42	-795,483.44
Inventory increase (+) or decrease (-)	73,013.91	16,464.97
External services	-187,440.69	-148,021.43
Total materials and services	-1,170,493.20	-927,039.90
Personnel expenses		
Wages and salaries	-2,385,084.20	-1,969,305.79
Social security costs		
Pension costs	-401,414.59	-337,265.66
Other personnel expenses	-63,370.98	-46,376.28
Total personnel expenses	-2,849,869.77	-2,352,947.73
Depreciation and amortization		
Depreciation according to plan	-121,544.34	-100,457.50
Depreciation of consolidated goodwill	-79,212.25	-79,212.20
Total depreciation and amortization	-200,756.59	-179,669.70
Other operating expenses	-2,792,828.06	-1,897,852.74
OPERATING PROFIT (LOSS)	-3,033,819.03	-2,291,656.92
Financial income and expenses		
Other interest and financial income		
From others	102,722.19	70.45
Interest and other financial expenses		
For others	-856,512.93	-123,616.56
PROFIT (LOSS) BEFORE APPROPRIATIONS AND TAXES	-3,787,609.77	-2,415,203.03
Income taxes		
Taxes for the accounting period	-1,000.00	-1,000.00
PROFIT (LOSS) FOR THE ACCOUNTING PERIOD	-3,788,609.77	-2,416,203.03

Consolidated balance sheet

EUR	31 December 2023	31 December 2022
ASSETS		
FIXED ASSETS		
Intangible assets		
Intangible rights	401,012.66	348,087.27
Consolidated goodwill	0.00	79,212.25
Other intangible assets	83,016.25	0.00
Total intangible assets	484,028.91	427,299.52
Tangible assets		
Buildings and structures	248,420.95	280,131.84
Machinery and equipment	157,045.79	221,229.72
Advance payments and work in progress	383,393.74	0.00
Total tangible assets	788,860.48	501,361.56
TOTAL FIXED ASSETS	1,272,889.39	928,661.08
CURRENT ASSETS		
Inventories		
Materials and supplies	409,641.86	336,627.95
Finished products	432,568.26	440,301.11
Total inventories	842,210.12	776,929.06
Short-term receivables		
Account receivables	1,216,505.92	352,677.51
Other receivables	300,714.21	137,789.12
Accrued income	114,927.83	68,730.94
Total short-term receivables	1,632,147.96	559,197.57
Money market deposits	3,125,871.00	1,015,376.19
Cash and cash equivalents	3,784,057.60	207,338.81
TOTAL CURRENT ASSETS	9,384,286.68	2,558,841.63
TOTAL ASSETS	10,657,176.07	3,487,502.71

EUR	31 December 2023	31 December 2022
LIABILITIES		
EQUITY		
Share capital	3,748,592.19	3,748,592.19
Other funds		
Invested unrestricted equity	19,700,759.65	9,603,259.65
Profit (loss) for previous accounting periods	-11,430,827.29	-9,014,624.26
Profit (loss) for the accounting period	-3,788,609.77	-2,416,203.03
TOTAL EQUITY	8,229,914.78	1,921,024.55
LIABILITIES		
Long-term liabilities		
Loans from financial institutions	256,692.81	11,990.46
Capital loans	414,465.50	690,776.50
Total long-term liabilities	671,158.31	702,766.96
Short-term liabilities		
Capital loans	276,311.00	0.00
Loans from financial institutions	98,728.00	10,157.71
Advances received	15,672.32	5,586.59
Accounts payable	477,959.03	199,955.84
Other liabilities	70,578.27	58,395.69
Accrued liabilities	816,854.36	589,615.37
Total short-term liabilities	1,756,102.98	863,711.20
TOTAL LIABILITIES	2,427,261.29	1,566,478.16
TOTAL EQUITY AND LIABILITIES	10,657,176.07	3,487,502.71

Consolidated cash flow statement

EUR	1 January–31 December 2023	1 January–31 December 2022
Cash flow from operating activities		
Profit for the accounting period	-3,788,609.77	-2,416,203.03
Adjustments		
Total depreciation and amortization	200,756.59	179,669.70
Financial income and expenses	753,790.74	123,546.11
Other adjustments	1,000.00	1,000.00
Cash flow before changes in working capital	-2,833,062.44	-2,111,987.22
Change in working capital		
Change in short-term non-interest-bearing receivables	-1,072,950.39	-97,757.01
Change in inventories	-65,281.06	-136,774.05
Change in short-term non-interest-bearing payables	540,371.15	-10,960.12
Operational cash flow before net financial expenses and taxes	-3,430,922.74	-2,357,478.40
Paid interests and payments from other operating financial expenses	-5,404.87	-1,339.32
Paid direct taxes	-1,000.00	-1,000.00
Cash flow from operating activities (A)	-3,437,327.61	-2,359,817.72
Cash flow from investments		
Investments for intangible and tangible assets	-161,350.13	-260,401.83
Cash flow from investments (B)	-161,350.13	-260,401.83
Cash flow from financing		
Paid share issue	10,097,500.00	0.00
Paid short-term loans	-36,957.36	-43,151.88
Paid long-term loans	0.00	-1,221,237.36
Paid interests and other payments on financing**	-774,651.30	-1,513,581.73
Cash flow from financing (C)	9,285,891.34	-2,777,970.97
Change in liquid assets (A+B+C) increase (+) or decrease (-)	5,687,213.60	-5,398,190.52
Cash and cash equivalents at the beginning of the accounting period*	1,222,715.00	6,620,905.52
Cash and cash equivalents at the end of the accounting period*	6,909,928.60	1,222,715.00

*Cash and cash equivalents include funds on bank accounts and liquid financial securities, which are reported as money market deposits in the balance sheet.

**Current year includes costs of financing transaction completed in April 2023. Comparison data includes interests paid on convertible capital loans and Business Finland's capital loans.

Parent company income statement

EUR	1 January–31 December 2023	1 January–31 December 2022
REVENUE	3,906,174.41	2,941,944.07
Change in stocks of finished and work-in-progress products, increase (+) or reduction (-)	-7,732.85	120,309.08
Other operating income	81,687.03	3,600.00
Materials and services		
Materials, supplies, and goods		
Purchases during the accounting period	-1,056,066.42	-795,483.44
Inventory increase (+) or decrease (-)	73,013.91	16,464.97
External services	-187,440.69	-148,021.43
Total materials and services	-1,170,493.20	-927,039.90
Personnel expenses		
Wages and salaries	-2,360,438.89	-1,969,305.79
Social security costs		
Pension costs	-401,414.59	-337,265.66
Other personnel expenses	-56,201.80	-46,376.28
Total personnel expenses	-2,818,055.28	-2,352,947.73
Depreciation and amortization		
Depreciation according to plan	-120,519.80	-98,945.43
Total depreciation and amortization	-120,519.80	-98,945.43
Other operating expenses	-2,838,584.24	-1,910,706.33
OPERATING PROFIT (LOSS)	-2,967,523.93	-2,223,786.24
Financial income and expenses		
Other interest and financial income		
From others	102,722.19	70.45
Interest and other financial expenses		
For others	-856,512.93	-123,616.56
PROFIT (LOSS) BEFORE APPROPRIATIONS AND TAXES	-3,721,314.67	-2,347,332.35
PROFIT (LOSS) FOR THE ACCOUNTING PERIOD	-3,721,314.67	-2,347,332.35

Parent company balance sheet

EUR	31 December 2023	31 December 2022
ASSETS		
FIXED ASSETS		
Intangible assets		
Intangible rights	395,442.00	342,118.71
Other intangible assets	83,016.25	0.00
Total intangible assets	478,458.25	342,118.71
Tangible assets		
Buildings and structures	248,420.95	280,131.84
Machinery and equipment	156,216.59	219,773.88
Advance payments and work in progress	383,393.74	0.00
Total tangible assets	788,031.28	499,905.72
Investments		
Shares in group member companies	437,992.60	437,992.60
Total investments	437,992.60	437,992.60
TOTAL FIXED ASSETS	1,704,482.13	1,280,017.03
CURRENT ASSETS		
Inventories		
Materials and supplies	409,641.86	336,627.95
Finished products	432,568.26	440,301.11
Total inventories	842,210.12	776,929.06
Short-term receivables		
Sales receivables	1,216,505.92	352,677.51
Receivables from group member companies	26,535.69	22,795.96
Other receivables	291,617.41	124,841.90
Accrued income	114,927.83	68,730.94
Total short-term receivables	1,649,586.85	569,046.31
Money market deposits	3,125,871.00	1,015,376.19
Cash and cash equivalents	3,746,237.18	205,652.09
TOTAL CURRENT ASSETS	9,363,905.15	2,567,003.65
TOTAL ASSETS	11,068,387.28	3,847,020.68

EUR	31 December 2023	31 December 2022
LIABILITIES		
EQUITY		
Share capital	3,748,592.19	3,748,592.19
Other funds		
Invested unrestricted equity	19,700,759.65	9,603,259.65
Profit (loss) for previous accounting periods	-11,065,243.23	-8,717,910.88
Profit (loss) for the accounting period	-3,721,314.67	-2,347,332.35
TOTAL EQUITY	8,662,793.94	2,286,608.61
LIABILITIES		
Long-term liabilities		
Loans from financial institutions	256,692.81	11,990.46
Capital loans	414,465.50	690,776.50
Total long-term liabilities	671,158.31	702,766.96
Short-term liabilities		
Loans from financial institutions	98,728.00	10,157.71
Capital loans	276,311.00	0.00
Advances received	15,672.32	5,586.59
Accounts payable	462,859.03	197,795.84
Other liabilities	66,010.32	56,489.60
Accrued liabilities	814,854.36	587,615.37
Total short-term liabilities	1,734,435.03	857,645.11
TOTAL LIABILITIES	2,405,593.34	1,560,412.07
TOTAL EQUITY AND LIABILITIES	11,068,387.28	3,847,020.68

Notes to the Financial Statements

Group and parent company

Accounting principles

The financial statements have been prepared in accordance with the principles and methods of measurement and recognition set out in Chapter 4 of the Government Decree on the information presented in the financial statements of a small undertaking and micro-undertaking, with the exception of the accounting principles for non-current assets set out below.

Intra-Group ownership has been eliminated using the acquisition cost method. Goodwill is depreciated on a straight-line basis over 5 years. Intra-Group transactions and receivables and liabilities between Group companies have been eliminated.

Measurement principles and methods used in the recognition of fixed and current assets

NON-CURRENT ASSETS

Intangible assets

The acquisition cost of items shown in non-current assets will be depreciated according to plans.

The depreciations have been calculated according to the following plans:

- Intangible rights: 10–20 years straight-line depreciation
- Buildings and structures: 10 years straight-line depreciation
- Machinery and equipment: 3–10 years straight-line depreciation
- Goodwill: 5 years straight-line depreciation

The depreciation period of patents in Austria is based on the period of validity of the patents (20 years). In other respects, the Group complies with a 10-year depreciation period in patents.

During the financial year 2023, external costs related to ERP project development and registration of market authorization applications have been capitalized. Depreciations will only start once the assets are completed and taken into use or when the market authorization has been approved.

Notes on the Group company

Parent company

Bioretec Ltd

Domicile

Tampere, Finland

Subsidiary

Bioretec GmbH

Bioretec Inc.

Ownership

100%

100%

Domicile

Graz, Austria

Delaware, United States

Related party transactions

The related parties of Bioretec include the parent company Bioretec Ltd and the subsidiaries Bioretec GmbH and Bioretec Inc. The related parties also include key persons in the management, their close family members, and/ or legal persons under his/ her influence. Key management personnel include members of Bioretec's Board of Directors, company CEO, and members of the Group Management Team.

The company has a consulting agreement with Tomi Numminen, the Chairman of the Board of Directors, regarding the commercialization of the company's products in the United States. In accordance with the resolution of the General Meeting, the maximum monthly consulting fee is EUR 7,500, and the total fees paid based on the agreement during 1 January–31 December 2023 were EUR 90,000 (in 2022, EUR 90,000).

The company has a consultancy agreement with Valugen GmbH, which is controlled by the Board member Michael Piccirillo. The services provided under the agreement have included business planning and creating of a contact network, among other things. In 2023, approximately EUR 44,000 (18,000) was invoiced.

Biorettec has a receivable from its subsidiary Biorettec GmbH. On 31 December 2023, the receivable amount totaled EUR 26,535.69 (EUR 22,795.96 on 31 December 2022). In addition, Biorettec GmbH has charged the parent company approximately EUR 271,000 (EUR 238,000) for research and other costs during the financial year.

Exceptional items

The result for the financial period was burdened by the costs of equity financing arrangements totaling EUR 775,000.

Commitments and contingencies

Group and parent company

Collateral provided and off-balance sheet commitments and arrangements as well as pension liabilities	31 December 2023	31 December 2022
Nominal amounts of open leasing agreements	130,003.07	32,175.67
Due in the next financial period	46,596.56	14,587.49
Due later	83,406.51	17,588.18
Lease liabilities for business premises	956,806.60	899,242.95

Lease agreement amounts increased from 2022, consisting of leases on IT and two company cars.

The original rental agreement for the company's business premises was fixed term for the period from 1 August 2021 to 31 December 2027. The current rental liability for the premises has been calculated for the period from 1 January 2024 to 31 December 2027. Additionally, the company has rented additional factory space from 1 February 2024 (until 31 December 2027), and the related lease liability totaling EUR 263 thousand has been included in the total amount of lease liabilities for business premises.

Other contingent liabilities	31 December 2023	31 December 2022
Liabilities total	12,964.16	4,226.00
Amount in use	12,964.16	4,226.00

Parent company

Group receivables	31 December 2023	31 December 2022
Group account receivables	26,535.69	22,795.96
Group loan receivables total	26,535.69	22,795.96

Group and parent company

Personnel	31 December 2023	31 December 2022
Average number of employees during the accounting period	31	26

Changes in equity

Group

Breakdown of equity	31 December 2023	31 December 2022
Share capital on 1 January	3,748,592.19	3,748,592.19
Share capital on 31 December	3,748,592.19	3,748,592.19
Total restricted equity	3,748,592.19	3,748,592.19
Invested unrestricted equity reserve on 1 January	9,603,259.65	9,603,259.65
Additions/reductions during the accounting period	10,097,500.00	0.00
Invested unrestricted equity reserve on 31 December	19,700,759.65	9,603,259.65
Profit /loss for the previous accounting period on 1 January	-11,430,827.31	-9,014,624.28
Profit /loss for the previous accounting period on 31 December	-11,430,827.31	-9,014,624.28
Profit/loss for the accounting period	-3,788,609.77	-2,416,203.03
Total retained earnings for the previous and current accounting period	-15,219,437.08	-11,430,827.31
Total equity	8,229,914.76	1,921,024.53

Parent company

Breakdown of equity	31 December 2023	31 December 2022
Share capital on 1 January	3,748,592.19	3,748,592.19
Share capital on 31 December	3,748,592.19	3,748,592.19
Total restricted equity	3,748,592.19	3,748,592.19
Invested unrestricted equity reserve on 1 January	9,603,259.65	9,603,259.65
Additions/reductions during the accounting period	10,097,500.00	0.00
Invested unrestricted equity reserve on 31 December	19,700,759.65	9,603,259.65
Profit/loss for the previous accounting periods on 1 January	-11,065,243.23	-8,717,910.88
Profit/loss for the previous accounting periods on 31 December	-11,065,243.23	-8,717,910.88
Profit/loss for the accounting period	-3,721,314.67	-2,347,332.35
Total retained earnings for the previous and current accounting period	-14,786,557.90	-11,065,243.23
Total equity	8,662,793.94	2,286,608.61

Number of the company's shares at year-end	31 December 2023	31 December 2022
	19,536,858	14,111,858

Calculation of distributable capital in accordance with Chapter 13 Section 5 of the Limited Liability Companies Act	31 December 2023	31 December 2022
Total distributable capital	4,914,201.75	-1,461,983.58
Total unrestricted capital at the end of the accounting period	4,914,201.75	-1,461,983.58
Invested unrestricted capital reserve (Ltd)	19,700,759.65	9,603,259.65
Profit/loss for the previous accounting periods	-11,065,243.23	-8,717,910.88
Profit/loss for the accounting period	-3,721,314.67	-2,347,332.35

Capital loans	31 December 2023	31 December 2022
Total capital loans	690,776.50	690,776.50
Capital loans presented as liabilities	690,776.50	690,776.50

Main terms of capital loans

Terms of capital loans, old Limited Liability Companies Act:

At the end of the financial period, the parent company had a capital loan from the State Treasury of Finland amounting to EUR 691,000. Items estimated to be maturing in 2024, a total of EUR 276 thousand, are presented as short-term debt.

The main terms of the capital loan are presented below:

The capital is payable only if, after payment, there is full coverage left for restricted equity and other non-distributable items in the approved balance sheet for the most recent accounting period of the company. Interest is payable only if the amount to be paid can be used for the distribution of profits according to the approved balance sheet for the most recent accounting period of the company. The loan period is two (2) years. The interest is one (1) percent lower than the base rate approved by the Ministry of Finance at the time but at least three (3) percent. On 31 December 2023, accrued and recorded total interest was EUR 41,447.

Calculation of the adequacy of the company's assets	31 December 2023	31 December 2022
Total equity	9,353,570.44	2,977,385.11
Equity	8,662,793.94	2,286,608.61
+Capital loan	690,776.50	690,776.50

Signatures for the Board of Directors' Report and Financial Statements

Place: Amsterdam

Time: 15 March 2024

Timo Lehtonen
CEO

Tomi Numminen
Chairman of the Board

Sarah van Hellenberg Hubar-Fisher
Member of the Board

Päivi Malinen
Member of the Board

Michael Piccirillo
Member of the Board

Kustaa Poutiainen
Member of the Board

Pekka Simula
Member of the Board

Auditor's note

A report on the performed audit has been issued today.

Place: Helsinki

Time: 15 March 2024

Ernst & Young Oy, Authorized Public Accountant Firm

Erika Grönlund
Authorized Public Accountant (APA)

Auditor's report

to the Annual General meeting of Bioretec Ltd

(Translation of the Finnish original)

Report on the Audit of Financial Statements

Opinion

We have audited the financial statements of Bioretec Oy (business identity code 1474196-9) for the year ended 31 December, 2023. The financial statements comprise the balance sheet, income statement, cash flow statement and notes for the group as well as the balance sheet, the income statement and notes for the parent company.

In our opinion, the financial statements give a true and fair view of the group's and parent company's financial performance and financial position in accordance with the laws and regulations governing the preparation of financial statements in Finland and comply with statutory requirements.

Basis for Opinion

We conducted our audit in accordance with good auditing practice in Finland. Our responsibilities under good auditing practice are further described in the Auditor's Responsibilities for the Audit of Financial Statements section of our report. We are independent of the parent company and of the group in accordance with the ethical requirements that are applicable in Finland and are relevant to our audit, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Responsibilities of the Board of Directors and the Managing Director for the Financial Statements

The Board of Directors and the Managing Director are responsible for the preparation of financial statements that give a true and fair view in accordance with the laws and regulations governing the preparation of financial statements in Finland and comply with statutory requirements. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the Board of Directors and the Managing Director are responsible for assessing the parent company's and the group's ability to continue as going concern, disclosing, as applicable, matters relating to going concern and using the going concern basis of accounting. The financial statements are prepared using the going concern basis of accounting unless there is an intention to liquidate the parent company or the group or cease operations, or there is no realistic alternative but to do so.

Auditor's Responsibilities for the Audit of Financial Statements

Our objectives are to obtain reasonable assurance on whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with good auditing practice will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the financial statements.

As part of an audit in accordance with good auditing practice, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the parent company's or the group's internal control.

- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Conclude on the appropriateness of the Board of Directors' and the Managing Director's use of the going concern basis of accounting and based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the parent company's or the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the company to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events so that the financial statements give a true and fair view.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

Other reporting requirements

Other information

The Board of Directors and the Managing Director are responsible for the other information. The other information comprises the report of the Board of Directors.

Our opinion on the financial statements does not cover the other information.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated. Our responsibility also includes considering whether the report of the Board of Directors has been prepared in accordance with the applicable laws and regulations.

In our opinion, the information in the report of the Board of Directors is consistent with the information in the financial statements and the report of the Board of Directors has been prepared in accordance with the applicable laws and regulations.

If, based on the work we have performed, we conclude that there is a material misstatement of the report of the Board of Directors, we are required to report that fact. We have nothing to report in this regard.

Helsinki 15 March 2024

Ernst & Young Oy
Authorized Public Accountant Firm

Erika Grönlund
Authorized Public Accountant

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