bioretec

Bioretec Ltd

Board of Directors' Report and Financial Statements

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Accounting period: 1 January–31 December 2022
Financial statements must be retained until 31 December 2032.
Financial statements have been prepared by Arol Finance Oy.

Board of Directors' Report for the financial year 2022

Bioretec in brief

Bioretec Ltd is a globally operating Finnish medical device company that develops, manufactures and markets bioresorbable orthopedic implants. Bioretec's implants enhance bone growth and accelerate fracture healing after orthopedic surgery. They are resorbed and replaced by bone, which eliminates the need for implant removal surgery. Bioretec's products are used worldwide in approximately 40 countries. The majority of Bioretec's net sales comes from exports. In 2022, 3% of net sales came from Finland and 97% from other countries. The company's customers include public and private hospitals and hospital districts. Bioretec's products are sold through the company's distribution network.

Bioretec's existing Activa product portfolio consists of bioabsorbable biopolymer products available for pediatric, trauma and sports surgery. Bioretec is also developing the new RemeOs™ product line based either purely on magnesium alloy or magnesium alloy and hybrid composite, introducing a new generation of strong bioresorbable materials. Some of the new products in the RemeOs™ product family will also be suitable for applications that require load-bearing capacity, such as the treatment of long bone fractures. The RemeOs™ implants have the potential to make titanium implants redundant. The U.S. and EU market authorizations for the first RemeOs™ product are expected in 2023.

Founded in 2003, Bioretec is headquartered in Tampere, Finland. At the end of 2022, the company had 28 employees in Finland. Bioretec's shares are traded on the Nasdaq First North Growth Market Finland marketplace. At the end of 2022, Bioretec Group consisted of the parent company Bioretec Ltd (domicile: Finland) and its wholly owned subsidiary Bioretec GmbH (formerly BRI.Tech GmbH, domiciled in Austria).

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

Consolidated key figures

EUR 1,000	FY 2022	FY 2021	Change, %
Net sales	**2,942**	2,003	46.9%
Sales margin	**2,139**	1,376	55.4%
Sales margin, %	**72.7%**	68.7%	
EBITDA	**-2,112**	-2,497	-15.4%
EBIT	**-2,292**	-2,666	-14.0%
Net profit (loss)	**-2,416**	-6,017	-59.8%
R&D spend on total costs, %	**28.1%**	34.7%	
Equity ratio, %	**55.2%**	50.6%	
Cash and cash equivalents	**1,223**	6,621	-81.5%
Earnings per share (undiluted)	**-0,17**	-0.43	-59.8%
Earnings per share (diluted)	**-0,12**	-0.31	-59.7%
Number of shares at the end of the period[1]	**14,111,858**	14,111,858	
Number of shares (diluted)	**19,608,126**	19,679,006	
Personnel[1]	**28**	26	7.7%

[1] Number of personnel at the end of the period.

Net sales, profitability and financial performance

NET SALES AND SALES MARGIN

Net sales for the financial period from January to December 2022 amounted to EUR 2,942 (2,003) thousand. The year-on-year growth was mainly due to the increased demand in Asia. 39% (50%) of net sales came from Europe, 2% (5%) from the U.S., and 59% (45%) from the rest of the world. Net sales in Europe increased 12% year on year due to increased market demand gained together with new distributors in Europe. Healthcare staffing shortages hindered the growth, especially in the Scandinavian market. In Russia, since the 24th of February 2022, Bioretec continued only to fulfill the existing contractual sales obligations. Sales in Russia in 2022 were EUR 456 (333) thousand. Net sales in the United States decreased by 34% due to the ongoing restructuring of the distribution network. Net sales in the rest of the world increased by 95%. The growth was mainly driven by China, with an 80% contribution to the net sales in that geographical area. The growth in China was mainly due to the increased number of new customers using Bioretec's bioresorbable products.

EUR 1,000	FY 2022	FY 2021	Change, %
Europe[1]	**1,138**	1,012	12.4%
U.S.	**63**	96	-34.0%
Rest of the world	**1,741**	895	94.6%
Total	**2,942**	**2,003**	**46.9%**

[1] Russia included in Europe.

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

OPERATING EXPENSES

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

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

EBITDA AND NET PROFIT (LOSS)

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

Financial position and cash flow

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

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

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

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

Research & development

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

PRODUCT DEVELOPMENT IN THE NEW REMEOS™ PRODUCT FAMILY

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

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

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

PRODUCT DEVELOPMENT IN THE CURRENT ACTIVA PRODUCT FAMILY

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

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

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

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

Operating environment and market development

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

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

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

Significant risks and uncertainties

Bioretec's Board of Directors has overall responsibility for the appropriateness of the company's risk management system, 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 the amount of available funds and customer credits and open accounts payables as well as reviewing the monthly forecasted cash flow. The Board of Directors has continued actions to explore funding opportunities and to secure the adequacy of funding. Currently, the company´s funding will not be sufficient for the full year of 2023.

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

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

Personnel

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

Changes in the Management Team

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

Annual General Meeting and Board authorizations

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

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

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

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

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

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

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

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

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

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

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

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

Granting option rights to the members of the Board of Directors

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

Board of Directors

On 31 December 2022, Bioretec's Board of Directors had five members. The Annual General Meeting held on 13 April 2022 re-elected Tomi Numminen, Michael Piccirillo, Sarah van Hellenberg Hubar-Fischer and Pekka Simula to new terms of office and Päivi Malinen as a new member of the Board of Directors. In its organizational meeting after the Annual General Meeting, the Board of Directors elected Tomi Numminen as the Chairman of the Board.

The Auditor

Bioretec's Annual General Meeting held on 13 April 2022 elected Authorized Public Accountants Ernst & Young Oy as the auditor of the company for a term ending at the close of the Annual General Meeting of 2023. Ernst & Young Oy has appointed Erika Grönlund, Authorized Public Accountant, as the responsible auditor. The auditor will be compensated as reasonably invoiced.

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

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

Shareholders

Bioretec's shares are in the book-entry system maintained by Euroclear Finland, and Euroclear Finland maintains Bioretec's official shareholder register. At the end of 2022, Bioretec had a total of 2,519 (2,235) registered shareholders, of whom 89% (88%) were private individuals. There were 777,143 (809,881) nominee-registered and foreign-owned shares, which was 5.5% (6%) of all shares and 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.

At the end of 2022, the members of Bioretec's Board of Directors owned a total of 12,690 (6,000) company's shares. The CEO did not own any of the company's shares (at the end of 2021, 0 shares). Other members of the Group's Management Team owned a total of 5,624 (6,291) company shares. Consequently, the company's executive management held 0.13% (0.09 %) of all of the company's shares and total 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 (formerly BRI.Tech GmbH) in connection with the completion of its acquisition in 2019.

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

Open option programs

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

[1] The 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.

Significant events after the review period

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

Estimates of future development

Bioretec's future prospects and profitability are substantially dependent on the company's success in obtaining market authorizations for its new magnesium-based RemeOs™ products in the United States and Europe, and the schedule related to this. Bioretec expects to receive the market authorization for the first RemeOs™ product in the U.S. in April 2023 and in the EU during 2023. The company expects moderate growth in the initial phase of the commercialization as physicians typically introduce new products gradually to gain their own clinical experience.

Other RemeOs™ products are still in different stages of product development, and the aim is to commercialize them gradually between 2024–2027. The company's long-term prospects and profitability will depend on the future success of clinical trials and commercialization of these new magnesium and hybrid composite-based products and the company's ability to meet its planned schedule.

As a significant share of Bioretec's future revenue is expected to come from products still in the development and commercialization phase, the company expects to incur significant costs relating to further product development. This product development is estimated to cause operating losses during the next few years. In the near future, the company expects to focus on financing its growth strategy and developing its business. The company expects to have positive operational cash flow by the end of 2025.

It is difficult to assess whether the development in 2022 and market recovery will continue in 2023, because the uncertainty caused by geopolitical tensions can affect the company's business, markets and costs. In addition, the occurrence of the coronavirus may still cause new national restrictions and thus weaken the demand for the company's products. Further, global inflation may weaken the company's profitability in the medium term.

In the long term, the orthopedic trauma products are a growing market, and according to forecasts, the market share of bioresorbable trauma products is growing and will continue to grow significantly 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 health care and brings new challenges for the global health care industry. The bioresorbable product innovations developed by Bioretec respond to these market drivers and further significantly increase the demand for bioresorbable products.

The Board's proposal for distribution of profit

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

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 2022	1 January–31 December 2021
REVENUE	**2,941,944.07**	**2,002,907.77**
Change in stocks of finished and work-in-progress products increase (+) or reduction (-)	120,309.08	-121,641.28
Other operating income	3,600.00	781.82
Materials and services		
Materials, supplies and goods		
Purchases during the accounting period	-795,483.44	-484,478.61
Inventory increase (+) or decrease (-)	16,464.97	89,607.87
External services	-148,021.43	-111,192.95
Total materials and services	**-927,039.90**	**-506,063.69**
Personnel expenses		
Wages and salaries	-1,969,305.79	-1,837,761.53
Social security costs		
Pension costs	-337,265.66	-302,149.12
Other personnel expenses	-46,376.28	-45,868.38
Total personnel expenses	**-2,352,947.73**	**-2,185,779.03**
Depreciation and amortization		
Depreciation according to plan	-100,457.50	-89,872.37
Depreciation of consolidated goodwill	-79,212.20	-79,212.20
Total depreciation and amortization	**-179,669.70**	**-169,084.57**
Other operating expenses	**-1,897,852.74**	**-1,687,037.50**
OPERATING PROFIT (LOSS)	**-2,291,656.92**	**-2,665,916.48**
Financial income and expenses		
Other interest and financial income		
From others	70.45	102.64
Interest and other financial expenses		
For others	-123,616.56	-3,350,204.42
PROFIT (LOSS) BEFORE APPROPRIATIONS AND TAXES	**-2,415,203.03**	**-6,016,018.26**
Income taxes		
Taxes for the accounting period	-1,000.00	-500.00
PROFIT (LOSS) FOR THE ACCOUNTING PERIOD	**-2,416,203.03**	**-6,016,518.26**

Consolidated balance sheet

EUR	31 December 2022	31 December 2021
ASSETS		
FIXED ASSETS		
Intangible assets		
Intangible rights	348,087.27	128,111.91
Consolidated goodwill	79,212.25	158,424.45
Total intangible assets	**427,299.52**	**286,536.36**
Tangible assets		
Buildings and structures	280,131.84	311,842.68
Machinery and equipment	221,229.72	259,569.91
Total tangible assets	**501,361.56**	**571,412.59**
TOTAL FIXED ASSETS	**928,661.08**	**857,948.95**
CURRENT ASSETS		
Inventories		
Materials and supplies	336,627.95	320,162.98
Finished products	440,301.11	319,992.03
Total inventories	**776,929.06**	**640,155.01**
Short-term receivables		
Accounts receivables	352,677.51	312,986.02
Other receivables	137,789.12	111,881.76
Accrued income	68,730.94	36,572.78
Total short-term receivables	**559,197.57**	**461,440.56**
Money market deposits	**1,015,376.19**	**6,458,418.40**
Cash and cash equivalents	**207,338.81**	**162,487.12**
TOTAL CURRENT ASSETS	**2,558,841.63**	**7,722,501.09**
TOTAL ASSETS	**3,487,502.71**	**8,580,450.04**

EUR	31 December 2022	31 December 2021
LIABILITIES		
EQUITY		
Share capital	3,748,592.19	3,748,592.19
Other funds		
Invested unrestricted equity	9,603,259.65	9,603,259.65
Profit (loss) for previous accounting periods	-9,014,624.26	-2,998,106.00
Profit (loss) for the accounting period	-2,416,203.03	-6,016,518.26
TOTAL EQUITY	**1,921,024.55**	**4,337,227.58**
LIABILITIES		
Long-term liabilities		
Loans from financial institutions	11,990.46	22,148.17
Capital loans	690,776.50	0.00
Total long-term liabilities	**702,766.96**	**22,148.17**
Short-term liabilities		
Capital loans	0.00	1,912,013.86
Loans from financial institutions	10,157.71	43,151.88
Advances received	5,586.59	10,689.11
Accounts payable	199,955.84	122,948.48
Other liabilities	58,395.69	49,542.57
Accrued liabilities	589,615.37	2,082,728.39
Total short-term liabilities	**863,711.20**	**4,221,074.29**
TOTAL LIABILITIES	**1,566,478.16**	**4,243,222.46**
TOTAL EQUITY AND LIABILITIES	**3,487,502.71**	**8,580,450.04**

Consolidated cash flow statement

EUR	1 January–31 December 2022	1 January–31 December 2021

Cash flow from operating activities		
Profit for the accounting period	-2,416,203.03	-6,016,518.26
Adjustments		
Total depreciations and amortization	179,669.70	169,084.57
Financial income and expenses	123,546.11	3,350,101.78
Other adjustments	1,000.00	500.00
Cash flow before changes in working capital	**-2,111,987.22**	**-2,496,831.91**
Change in working capital		
Change in short-term non-interest-bearing receivables	-97,757.01	-163,921.78
Change in inventories	-136,774.05	32,033.41
Change in short-term non-interest-bearing payables	-10,960.12	245,976.66
Operational cash flow before net financial expenses and taxes	**-2,357,478.40**	**-2,382,743.62**
Paid interests and payments from other operating financial expenses	-1,339.32	-3,782.00
Paid direct taxes	-1,000.00	-500.00
Cash flow from operating activities (A)	**-2,359,817.72**	**-2,387,025.62**
Cash flow from investments		
Investments for intangible and tangible assets	-260,401.83	-393,282.70
Cash flow from investments (B)	**-260,401.83**	**-393,282.70**
Cash flow from financing		
Paid share issue	0.00	8,993,611.97
Paid short-term loans	-43,151.88	-75,719,95
Paid long-term loans	-1,221,237.36	0
Paid interests and payments from financial expenses**	-1,513,581.73	-1,789,779.16
Cash flow from financing (C)	**-2,777,970.97**	**7,128,112.86**
Change in liquid assets (A+B+C) increase (+) or decrease (-)	**-5,398,190.52**	**4,347,804.54**
Cash and cash equivalents at the beginning of the accounting period*	**6,620,905.52**	**2,273,100.98**
Cash and cash equivalents at the end of the accounting period*	**1,222,715.00**	**6,620,905.52**

*Cash and cash equivalents include funds on bank accounts and liquid financial securities, which are reported as money market deposits in the balance sheet.
** Interests paid include interest payments of convertible capital loans and Business Finland's capital loans.

Parent company income statement

EUR	1 January–31 December 2022	1 January–31 December 2021

REVENUE	**2,941,944.07**	**2,002,907.77**
Change in stocks of finished and work-in-progress products increase (+) or reduction (-)	120,309.08	-121,641.28
Other operating income	3,600.00	0.00
Materials and services		
Materials, supplies, and goods		
Purchases during the accounting period	-795,483.44	-484,478.61
Inventory increase (+) or decrease (-)	16,464.97	89,607.87
External services	-148,021.43	-111,192.95
Total materials and services	**-927,039.90**	**-506,063.69**
Personnel expenses		
Wages and salaries	-1,969,305.79	-1,837,761.53
Social security costs		
Pension costs	-337,265.66	-302,149.12
Other personnel expenses	-46,376.28	-45,868.38
Total personnel expenses	**-2,352,947.73**	**-2,185,779.03**
Depreciation and amortization		
Depreciation according to plan	-98,945.43	-67,701.83
Reduction in value of non-current assets	0.00	-4,497.24
Total depreciation and amortization	**-98,945.43**	**-72,199.07**
Other operating expenses	**-1,910,706.33**	**-1,714,841.54**
OPERATING PROFIT (LOSS)	**-2,223,786.24**	**-2,597,616.84**
Financial income and expenses		
Other interest and financial income		
From others	70.45	102.64
Interest and other financial expenses		
For others	-123,616.56	-3,350,204.42
PROFIT (LOSS) BEFORE APPROPRIATIONS AND TAXES	**-2,347,332.35**	**-5,947,718.62**
PROFIT (LOSS) FOR THE ACCOUNTING PERIOD	**-2,347,332.35**	**-5,947,718.62**

Parent company balance sheet

EUR	31 December 2022	31 December 2021
ASSETS		
FIXED ASSETS		
Intangible assets		
Intangible rights	342,118.71	121,745.45
Total intangible assets	**342,118.71**	**121,745.45**
Tangible assets		
Buildings and structures	280,131.84	311,842.68
Machinery and equipment	219,773.88	259,348.21
Total tangible assets	**499,905.72**	**571,190.89**
Investments		
Shares in group member companies	437,992.60	437,992.60
Total investments	**437,992.60**	**437,992.60**
TOTAL FIXED ASSETS	**1,280,017.03**	**1,130,928.94**
CURRENT ASSETS		
Inventories		
Materials and supplies	336,627.95	320,162.98
Finished products	440,301.11	319,992.03
Total inventories	**776,929.06**	**640,155.01**
Short-term receivables		
Sales receivables	352,677.51	312,986.02
Receivables from group member companies	22,795.96	28,615.76
Other receivables	124,841.90	111,083.13
Accrued income	68,730.94	36,572.78
Total short-term receivables	**569,046.31**	**489,257.69**
Money market deposits	**1,015,376.19**	**6,458,418.40**
Cash and cash equivalents	**205,652.09**	**151,334.91**
TOTAL CURRENT ASSETS	**2,567,003.65**	**7,739,166.01**
TOTAL ASSETS	**3,847,020.68**	**8,870,094.95**

EUR	31 December 2022	31 December 2021

LIABILITIES		
EQUITY		
Share capital	3,748,592.19	3,748,592.19
Other funds		
Invested unrestricted equity	9,603,259.65	9,603,259.65
Profit (loss) for previous accounting periods	-8,717,910.88	-2,770,192.26
Profit (loss) for the accounting period	**-2,347,332.35**	**-5,947,718.62**
TOTAL EQUITY	**2,286,608.61**	**4,633,940.96**
LIABILITIES		
Long-term liabilities		
Loans from financial institutions	11,990.46	22,148.17
Capital loans	690,776.50	0.00
Total long-term liabilities	**702,766.96**	22,148.17
Short-term liabilities		
Loans from financial institutions	10,157.71	43,151.88
Capital loans	0.00	1,912,013.86
Advances received	5,586.59	10,689.11
Account payables	197,795.84	119,286.10
Other liabilities	56,489.60	47,636.48
Accrued liabilities	587,615.37	2,081,228.39
Total short-term liabilities	**857,645.11**	**4,214,005.82**
TOTAL LIABILITIES	**1,560,412.07**	**4,236,153.99**
TOTAL EQUITY AND LIABILITIES	**3,847,020.68**	**8,870,094.95**

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 2022, external costs related to the registration of market authorization applications have been capitalized, the depreciation of which will only start once the relevant market authorization has been approved.

Notes on the Group company

Parent company		**Domicile**
Bioretec Ltd		Tampere, Finland
Subsidiary	**Ownership**	**Domicile**
Bioretec GmbH	100%	Graz, Austria

The subsidiary BRI.Tech GmbH changed its name to Bioretec GmbH during the financial year 2022.

Going concern principle

As the parent company's operational cash flow is not sufficient to cover operating expenses, the continuation of operations requires additional financing from shareholders or new investors in the financial year 2023. The company's

financial statements have been prepared in accordance with the going concern principle, as the company believes that it will be able to raise additional financing.

Related party transactions

The related parties of Bioretec include the parent company Bioretec Ltd and the subsidiary Bioretec GmbH (previously BRI.Tech GmbH). The related parties also include key persons in the management and their close family members. 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 monthly consulting fee is EUR 7,500, and total fees paid based on the agreement during 1 January–31 December 2022 were EUR 90,000. In 2021, starting on 1 May 2022, total fees paid were EUR 60,000.

The company has a consultancy agreement with the company Valugen GmbH controlled by the Board member Michael Piccirillo. The services provided under the agreement have included business planning and creating of contact network, among other things. Approximately EUR 18,000 has been invoiced in 2022.

Bioretec has a receivable from its subsidiary Bioretec GmbH. On 31 December 2022 The receivable amount totaled EUR 22,795.96 (EUR 28,615.76 on 31 December 2021). In addition, Bioretec GmbH has charged the parent company approximately EUR 238,000 (EUR 105,000) for research and other costs during the financial year.

Exceptional items

Comparison period result was burdened by the costs of equity financing arrangements and the impact on profit of accrued interest on subordinated loan totaling EUR 3.35 million.

Commitments and contingencies

Group and parent company

Collateral provided and off-balance sheet commitments and arrangements as well as pension liabilities	31 December 2022	31 December 2021
Nominal amounts of open leasing agreements	32,175.67	19,811.64
Due in the next financial period	14,587.49	9,266.54
Due later	17,588.18	10,545.10
Rental liabilities for business premises	899,242.95	950,971.13

The rental agreement for the company's business premises' is fixed term for the period from 1 August 2021 to 31 December 2027. The rental liability for the premises has been calculated for the period from 1 January 2023 to 31 December 2027.

Other contingent liabilities	31 December 2022	31 December 2021
Liabilities total	4,226.00	23,963.62
Amount in use	4,226.00	3,963.62

Guarantees given by type and the amount of liability or a guarantee with lesser value	31 December 2022	31 December 2021
Loans from credit institutions	0.00	32,994.17

Company mortgages total	0.00	440,000.00

Parent company

Group receivables	31 December 2022	31 December 2021
Group account receivables	22,795.96	28,615.76
Group loan receivables total	**22,795.96**	**28,615.76**

Group and parent company

Personnel	31 December 2022	31 December 2021
Average number of employees during the accounting period	26	24

Changes in equity

Group

Breakdown of equity	31 December 2022	31 December 2021
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
Share issues on 1 January	0.00	609,647.70
Additions/reductions during the accounting period	0.00	-609,647.70
Invested unrestricted equity reserve on 1 January	9,603,259.65	0.00
Additions/reductions during the accounting period	0.00	9,603,259.65
Invested unrestricted equity reserve on 31 December	9,603,259.65	9,603,259.65
Profit /loss for the previous accounting period on 1 January	-9,014,624.28	-2,998,106.02
Profit /loss for the previous accounting period on 31 December	-9,014,624.28	-2,998,106.02
Profit/loss for the accounting period	-2,416,203.03	-6,016,518.26
Total retained earnings for the previous and current accounting period	-11,430,827.31	-9,014,624.28
Total equity	**1,921,024.53**	**4,337,227.56**

Parent company

Breakdown of equity	31 December 2022	31 December 2021
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
Share issues on 1 January	0.00	609,647.70
Additions/reductions during the accounting period	0.00	-609,647.70
Invested unrestricted equity reserve on 1 January	9,603,259.65	0.00
Additions/reductions during the accounting period	0.00	9,603,259.65
Invested unrestricted equity reserve on 31 December	9,603,259.65	9,603,259.65
Profit/loss for the previous accounting periods on 1 January	-8,717,910.88	-2,770,192.26
Profit/loss for the previous accounting periods on 31 December	-8,717,910.88	-2,770,192.26
Profit/loss for the accounting period	-2,347,332.35	-5,947,718.62
Total retained earnings for the previous and current accounting period	-11,065,243.23	-8,717,910.88
Total equity	**2,286,608.61**	**4,633,940.96**

Number of the company's shares at year end	31 December 2022	31 December 2021
	14,111,858	14,111,858

Calculation of distributable capital in accordance with Chapter 13 Section 5 of the Limited Liability Companies Act	31 December 2022	31 December 2021
Total distributable capital	-1,461,983.58	885,348.77
Total unrestricted capital at the end of the accounting period	-1,461,983.58	885,348.77
Invested unrestricted capital reserve (Ltd)	9,603,259.65	9,603,259.65
Profit/loss for the previous accounting periods	-8,717,910.88	-2,770,192.26
Profit/loss for the accounting period	-2,347,332.35	-5,947,718.62

Capital loans	31 December 2022	31 December 2021
Total capital loans	**690,776.50**	**1,912,013.86**
Capital loans presented as liabilities	690,776.50	1,912,013.86

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 EUR 691,000. In the financial year 2022, the capital of EUR 691,000 was repaid, and in addition, the interest accrued until 31 December 2021 totaling EUR 707,000 was paid.

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. If the payment conditions are met, the loan instalments are repaid annually and starting from year 2022, the loan period is five (5) 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. Accrued unrecorded interest for the year 2022 was in total EUR 20,723.

Convertible capital loan 2011 (CCL1 and CCL2)

At the end of the comparison period, the parent company had a subordinated convertible capital loan. The principal amount of the loan of EUR 530,000 and interest of EUR 807,000 have been paid in full during the financial period.

Main terms of the convertible capital loan 2011 CCL1 and CCL2 in the balance sheet in the comparison period:

The loan is subordinated in accordance with Chapter 12 of the Limited Liability Companies Act and is therefore a capital loan. In the event of liquidation and bankruptcy of the parent company, the principal amount of the loan and any interest accrued thereon may only be repaid after all the claims of other liabilities have been satisfied. However, such liabilities do not include other capital loans. In cases other than those mentioned above, the principal amount of the loan may be otherwise repaid, and interest paid only in so far as the sum total of the unrestricted equity and all the capital loans of the company (including the loan) at the time of payment exceeds the loss on the balance sheet to be adopted for the latest accounting period of the balance sheet as a separate item. The loan is recorded in the parent company's balance sheet as a separate item. In connection with the recording of the loan, the company agrees, by signing the loan agreement in consideration of the payment of the subscription, to issue to the creditor option rights or other special rights entitling to shares referred to in Chapter 10, Section 1 of the Limited Liability Companies Act (624/2006 as amended), which entitle and obligate the creditor to subscribe for new shares of the company under the terms and conditions of the agreement specified in more detail. The loan, or if a part of the loan has been repaid, the remaining amount shall bear a fixed annual interest of twelve (12) percent.

Calculation of the adequacy of the company's assets	31 December 2022	31 December 2021
Total equity	2 977 385.11	6,545,954.82
Equity	2 286 608.61	4,633,940.96
+Capital loan	690 776.50	1,912,013.86

Signatures for the Board of Directors' Report and Financial Statements

Place: Helsinki

Time: 17 March 2023

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

Pekka Simula
Member of the Board

Auditor's note

A report on the performed audit has been issued today.

Place: Helsinki

Time: 17 March 2023

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, 2022. 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.

Material Uncertainty Related to Going Concern

We want to draw attention to the note "Going concern principle" in the financial statements. The Group incurred a loss of 2.4 million euros during the period, and cash and money market deposits amount to 1.2 million euros as of 31 December 2022. As explained in the note, the parent company's operational cash flow is not sufficient to cover operating expenses during the financial year 2023, and the continuation of operations requires additional financing from shareholders or new investors in the financial year 2023. This indicates a material uncertainty relating to the company's ability to continue as going concern. Our opinion is not modified in this respect.

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 17 March 2023

Ernst & Young Oy
Authorized Public Accountant Firm

Erika Grönlund
Authorized Public Accountant

bioretec

better healing – better life

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