bioretec

Interim report

Q1 Breakthrough Device Designation granted by FDA

"The Company achieved a major milestone with RemeOs™ screws by receiving a Breakthrough Device Designation from FDA during March. This opens a direct dialog with FDA and puts Company to fast-track targeting to the marketing authorization of RemeOs™ screws in US"
Timo Lehtonen, CEO

SIGNIFICANT EVENTS (During and after the period)

- FDA granted Breakthrough Device Designation status to RemeOs™ screws and the Company started this FDA process targeting the marketing authorization of RemeOs™ screws in US.
- According to the information available, the Company estimates that the US market authorization for RemeOs™ shall be granted H1/2022.
- The market shows signs of recovery during this period and net sales grew 41% compared to corresponding period of 2020 from 368 k€ to 519 k€. Sales recorded for Q1 2021 was one of the highest ever recorded at Bioretec history.
- Relocation to new facilities is proceeding as planned and preparations for production transfer has been initiated. Estimated completion of the relocation of all operations to new facility is in Q3/2021.
- The Company continues to evaluate a possibility to conduct initial public offering.
- No other significant events have occurred after the period.

KEY FINANCIALS Q1 / January – March 2021

- Net sales increased by 41% from Q1 2020 and amounted to 519 k€ (368 k€ in Q1/2020).
- The Europe area reported net sales of 179 k€, which is a 10% increase in sales from Q1 2020 (163 k€).
- The ROW (Rest of the World) area reported net sales of 319 k€, which is a 72% increase in sales from Q1 2020 (185 k€).
- The US area reported net sales remained at last year level due to effects of COVID-19 on the healthcare system.
- The Sales Margin % 78.6% was slightly higher compared to Q1 2020 (75.9%) mainly due to changes in customer mix.
- Net profit (loss) amounted to -543 k€ (-850 k€ in Q1 2020).
- The Company continued to invest in development of the new RemeOs™ product line

KEY FIGURES (1000 Euros, non-audited)	Q1/2021	Q1/2020	FY 2020
Net Sales	**519**	368	**1 499**
Sales Margin	**408**	280	**1 103**
Sales Margin %	**78.6 %**	75.9 %	**73.5 %**
EBITDA	**-506**	-489	**-1 787**
EBIT	**-541**	-523	**-1 925**
Net profit (loss)	**-543**	-850	**-2 259**
R&D spend on total costs (%)	**37 %**	18 %	**24 %**
Equity ratio (%)	**23 %**	45 %	**35 %**
Cash and cash receivables	**1 630**	3 298	**2 273**
Earnings per share (undiluted)	**-3.5**	-5.7	**-15.0**
Earnings per share (diluted)	**-2.2**	-3.7	**-10.3**
Number of shares at the end of the period	**156 988 545**	150 007 527	**150 402 068**
Number of shares (diluted)	**244 721 513**	229 998 830	**218 724 369**
Personnel total	**24**	24	**23**

[1] Exact number of personnel at end of the period

CEO COMMENTS ON THE FIRST QUARTER

Looking forward confidently to the rest of the year 2021

The year 2020 was in every aspect challenging due to the global situation that affected sales and marketing, but the Company achieved many significant milestones during the past year regarding new sales authorizations and in finalizing tasks of the development of groundbreaking RemeOs™ magnesium alloy technology. The first quarter brought a number of interesting and exciting events to the Company, to name the most significant ones, RemeOs™ Breakthrough Device Designation status and initiation of the relocation to a new more well-suited facility.

We are now honored to have our RemeOs™ screw selected for the US FDA Breakthrough Device Program. We are excited that US patients and the US healthcare system may now have faster access to our novel, fully bioresorbable metal implant, which provides more effective treatment and improves patient´s quality of life. The FDA Breakthrough Device Designation program opens a direct dialog with FDA and puts the Company to fast-track targeting to the marketing authorization of RemeOs™ screws in US. After years of development, the orthopedic surgeon shall soon have a bioresorbable metal implant, which behaves like a traditional, non-resorbing metal implant and provides similar fixation strength and surgical procedures.

The Company's product development focused on new RemeOs™ magnesium alloy technology in accordance with the FDA Breakthrough Device Designation program framework. According to the Company's current estimation, the De Novo marketing authorization approval for RemeOs™ compression screw portfolio will be granted during the first half of 2022. The plan is also to submit a CE market authorization application to the Company's European notified body DEKRA after the submission of De Novo-application. These marketing authorization applications are based on a clinical trial started in 2018, for which the first-year follow-up of all patients were completed during the previous quarter. The RemeOs™ compression screws are intended to be used in indications located in the lower and upper extremities. The extremities are one of the orthopedic frontiers where there's still a lot of opportunity for innovation and improved surgical outcomes, while being an underserved market for many physicians. To support the commercialization of the RemeOs™ portfolio in these indications, the Company has initiated the International Scientific Advisory Board's creation from globally distinguished surgeons and medical professionals.

During the previous quarter the Company signed a lease agreement of the new facilities. The renovation of the new facility with ISO Class-8 cleanroom started during this quarter. The new facility project, including production transfer, is proceeding as planned and the target is to complete the transfer of all operations into the new facility during Q3/2021.

The past year has been challenging for healthcare, patients and society as a whole. I am proud of the strategic and operative progress we have achieved during the past quarter, and our organization's ability to adapt the business to prevailing conditions. We have a strong belief in the company's technologies and the benefits they bring to patients and society.

Timo Lehtonen, CEO

SALES AND MARKETING

Sales showed signs of recovery

After challenging times, the first quarter's sales showed signs of recovery despite the continuation of the COVID-19 pandemic and the transforming virus. The first-quarter sales resulted in an increase of 41% compared to the first quarter of 2020 and one of the highest ever recorded in Bioretec history. Especially in China, the sales have been excellent during the first quarter and it seems to be growing with the same trend as during the last year.

The first quarter brought significant sales improvements compared to the same period in the previous year, especially considering, that the COVID-19 outbreak had not yet begun to shake the world in Q1 2020. Geographically, sales continued the same trend as in previous quarters, with sales in Asia continuing to grow for the fourth quarter in a row. According to the Company's unaudited result, sales of Q1 2021 ended during the period at 519 k€, which is 23% higher than the previous quarter (Q4 2020) sales and giving a good start to the year 2021.

On the other hand, given the news of a possibly worsening pandemic due to new variants of the virus and policies the elected US administration will enact, it is difficult to predict the rest of the year 2021. Considering the aforementioned factors, significant uncertainty remains in the market, so we believe that the orthopedic market's growth potential in the first half of 2021 is limited but better than in 2020. The overall consensus in the industry suggests that 2021 growth rates will be fairly comparable to 2019.

The Company has during 2020 modified its marketing strategy to support virtual training events and webinars. During the latest quarter (Q1 2021), the Company continued with the same strategy and held several virtual training events and webinars and received excellent feedback from customers, doctors, and distributors on the events where leading orthopedic surgeons presented studies and patient cases of ACTIVA™ products. Local restrictions have forced all of us to adopt some form of virtual communication for connecting with colleagues, vendors, customers and, of course, doctors and patients. Webinars, web conferences and virtual reality trainings are good examples of how we need to adapt our procedures according to the ever-changing world. All of this technology brings the likelihood of lasting economic benefits, which means that they will continue to be a part of our everyday life.

SALES BY GEOGRAPHICAL AREA

(1000 Euros)	Q1/2021	Q1/2020	FY 2020
Europe[1]	**179**	163	**697**
US	**21**	20	**68**
ROW (rest of world)	**319**	185	**734**
TOTAL	**519**	368	**1 499**

[1] Russia included in Europe

RESEARCH AND DEVELOPMENT

RemeOs™ on a fast Track

Bioretec's research and development continued the path laid down by US Food and Drug Administration (FDA) pre-submission feedback from 2020 and focused all the activities aiming for US market authorization of new RemeOs™ magnesium alloy compression screws. A significant milestone was achieved when the Company received FDA Breakthrough Device Designation status for a bioresorbable metal implant RemeOs™ screws for proposed indications in traumatology and orthopedic indications.

Bioretec's RemeOs™ screw met the demanding criteria of the US FDA Breakthrough Device for proposed indications. Bioretec's RemeOs™ screws are intended for use in traumatic surgery/traumatology and orthopedic surgery for the fixation of bone fractures (osteosynthesis) and osteotomies, and for the correction of deformities or malalignments. The implants serve as temporary fixation and stabilization by osteosynthesis of bones and fragments until bony fusion has occurred.

According to the FDA, a Breakthrough Device provides a more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions. Additionally, a Breakthrough Device represents breakthrough technology or offers significant advantages over existing approved or cleared alternatives. The advantages include the potential to reduce or eliminate the need for hospitalization, improve patient quality of life, or establish long-term clinical efficiencies. Under the program, the FDA will provide Bioretec with priority review and interactive communication regarding device development and clinical trial protocols, through to commercialization decisions.

A new investigator initiated clinical study (IIS) was started during the first quarter supporting the indication expansion of pediatric Activa™ IM-nail for distal radius fracture treatment. The first operations with this novel treatment of children's wrist fractures have been now completed and the study will continue as planned.

Post Market Clinical follow-up study of Activa™ IM-nail in CE-marked indication continues as planned, but patient enrollment is slower than anticipated due to COVID-19 restrictions. The investigation is ongoing in Hungary and Austria, and ethical committee approvals are initiated in Germany, France, Portugal, and Denmark.

Continuing global measures against COVID-19 and the need to prioritize healthcare resources may impact ongoing and forthcoming clinical trials. At present, Bioretec has no information on any consequences of COVID-19 other than those presented above. Updates will be provided when applicable.

PERIODICAL OUTLOOK

Financial overview Q1/2021

PROFIT AND LOSS

Net sales and sales margin
Revenue of Bioretec group totaled 519 k€ having an increase of 151 k€ (41%) compared to Q1 2020. Increase was mainly coming from higher sales of Activa products in the Asian market. Absolute sales margin was 408 k€ having an increase of 46% (and 129 k€) compared to Q1 2020. Main reason for slightly improved sales margin level was caused by the changes in the customer mix.

Operating Expenses
Bioretec group total operating costs (including salaries, depreciation and other operating expenses) were 950 k€ and ended up with an increase of 147 k€ (and 18%) compared to Q1 2020 (803 k€). Increase was mainly due to high level of resourcing done to new product development. The Company measures its RD spend (against the total operating costs) with a separate key figure RD spend % (on above total costs). RD spend% for Q1 2021 was 37% (351 k€) against the 18% during Q1 2020 (143 k€).

EBITDA and Net profit (loss)
Bioretec group EBITDA was -506 k€ (-489 k€ at Q1 2020) and remained at last year level. Net loss of the period was -543 k€ (-850 k€ for Q1 2020) and at similar level than Q1 2020 if excluding the financial expenses (-332 k€ on Q1 2020) mainly from the equity arrangement of comparison period.

FINANCIAL POSITION AND CASH FLOWS

Investments totaled 91 k€ (32 k€ at Q1 2020) were mainly related to Bioretec relocation to new office and factory premises during Q3 2021. Operational cash flow totaled -587 k€ (-485 k€ at Q1 2020). Main reason for increase is coming from the increased level of inventories (as production shut down is planned as part of the relocation project).

PERSONNEL, MANAGEMENT AND THE BOARD OF DIRECTORS

The number of personnel at the end of the review period was 24 (24 at the end of Q1/2020) persons. Bioretec's members of the Board of Directors were Tomi Numminen (Executive Chairman), Heinz Moitzi, Pertti Törmälä, Pekka Simula, Michael Piccirillo and Hans Rosen.

SHARES AND RELATED PROGRAMMES

On 31 March 2021 Bioretec had 156 988 545 (150 402 068 on 31 December 2020) shares, distributed among some 900 shareholders. Each share entitles to one vote at the General Meeting of Shareholders. During the quarter, the number of shares increased as a result of converted options. The holders of Options Rights 2017-1, 2018-2 and 2019-2 exercised their Options Rights to subscribe in total for 10 814 031 shares. Shares relating to Option Rights 2017-1 were registered before 31 March 2021. However, the registration of shares based on option rights 2018-2 and 2019-2 (representing in total 4 227 554 shares) was completed during April 2021. On 31 March 2021, Bioretec's share capital was 3,7 M€. The Extraordinary General meeting on 22 January 2021 resolved to incorporate the shares of the company into the book-entry system maintained by Euroclear.

Bioretec has three option programs (2018-1, 2019-1 and 2020-1). The board of directors decided on 13 January 2021, based on the authorization given by the Annual General Meeting on 26 June 2020, to issue up to 9 million Option Rights relating to option program 2020-1, based on which in total 26 million shares can be issued without payment, to the company's Key Employees and members of the Key Opinion Leader group . Additionally, the Extraordinary General meeting decided on 22 January 2021 to grant 3 million Option Rights on the Terms and Conditions of the option program 2020-1 to members of the board of directors as follows: Michael Piccirillo 1 000 000 Options Rights, Hans Rosen 1 000 000 Options Rights and Pekka Simula 1 000 000 Options Rights. One Option Right entitles to one new share of the Company.

CONSOLIDATED INCOME STATEMENT [1]

(1000€ Euros)	Q1/2021	Q1/2020	FY 2020
REVENUE	**519**	368	**1 499**
Changes in stocks (FG and WIP)	**-24**	-7	**137**
Other operating income	**0**	0	**2**
Total materials and services	**-87**	-81	**-535**
Total personnel expenses	**-522**	-495	**-1 780**
Total depreciation and amortization	**-35**	-34	**-138**
Other operating expenses	**-392**	-273	**-1 109**
OPERATING PROFIT (LOSS)	**-541**	-523	**-1 925**
Net financial expenses	**-1**	-327	**-333**
Profit (loss) before taxes	**-543**	-850	**-2 258**
Income taxes	**0**	0	**-1**
PROFIT (LOSS) FOR THE PERIOD	**-543**	-850	**-2 259**

[1] non-audited

CONSOLIDATED BALANCE SHEET [1]

(1000 euros)	Q1/2021	Q1/2020	FY 2020
ASSETS			
NON-CURRENT ASSETS			
Intangible assets	**384**	459	**410**
Tangible assets	**312**	162	**240**
CURRENT ASSETS			
Total inventories	**730**	505	**672**
Short-term debtors	**679**	357	**298**
Cash in hand and at banks	**1 630**	3 298	**2 273**
TOTAL ASSETS	**3 737**	4 781	**3 892**
EQUITY AND LIABILITIES			
EQUITY			
Restricted share capital	**3 749**	9 221	**3 749**
Share issue	**4**	0	**610**
Other reserves (unrestricted equity fund)	**659**	17 008	**0**
Retained earnings (loss)	**-2 998**	-23 239	**-739**
Profit (loss) for the financial year	**-543**	-850	**-2 259**
LIABILITIES			
Long-term creditors	**1 961**	1 995	**1 977**
Short-term creditors	**905**	646	**555**
TOTAL EQUITY AND LIABILITIES	**3 737**	4 781	**3 892**

[1] non-audited

STATEMENT OF CHANGES IN EQUITY [1]

(1000 euros)	Q1/2021	Q1/2020	FY 2020
Share capital at the beginning of the period	**3 749**	9221	**9 221**
Reduction of equity	**0**	0	**-5 473**
Restricted equity total at the end of the period	**3 749**	9221	**3 749**
Share issues at the beginning of the period	**610**	0	**0**
Period changes	**-605**	0	**610**
Share issues at the end of the period	**4**	0	**610**
Invested unrestricted equity at the beginning of the period	**0**	12755	**12 755**
Reduction of equity	**0**	0	**-17 027**
Period changes	**659**	4253	**4 272**
Invested unrestricted equity at the end of the period	**659**	17008	**0**
Retained earnings at the beginning of the period	**-2 998**	-23 239	**-23 239**
Reduction of equity	**0**	0	**22 500**
Retained earnings at the end of the period	**-2 998**	-23 239	**-739**
Result of the period	**-543**	-850	**-2 259**
TOTAL EQUITY	**871**	2 140	**1 360**

[1] non-audited

FINANCIAL POSITION AND CASH FLOW [1]

(1000 euros)	Q1/2021	Q1/2020	FY 2020
CASH FLOW FROM OPERATING ACTIVITIES			
Cash flow before changes in working capital	**-506**	-489	**-1 787**
Change in Working Capital	**-81**	17	**-193**
Net financial expenses and taxes paid	**0**	-13	**-19**
CASH FLOW FROM OPERATING ACTIVITIES	**-587**	-484	**-1 998**
CASH FLOW FROM INVESTMENTS			
Investments for tangible and intangible assets	**-91**	-32	**-121**
CASH FLOW FROM INVESTMENTS	**-91**	-32	**-121**
CASH FLOW FROM FINANCING			
Paid share issues	**53**	4 003	**4 613**
Change in short- and long-term financing	**-18**	80	**48**
Paid other financial expenses	**0**	-327	**-327**
CASH FLOW FROM FINANCING	**35**	3 756	**4 335**
Change in liquid assets (+/-)	**-643**	3 240	**2 215**
Bank and bank receivables at the beginning of the period	**2 273**	58	**58**
Bank and bank receivables at the end of the period	**1 630**	3 298	**2 273**

[1] non-audited

OTHER DISCLOSURES

BASIS OF PREPARATION OF THE INTERIM REPORT

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

Accounting principles have not changed during the reporting period.

SIGNIFICANT RISKS AND UNCERTAINTIES

The Company is exposed to various financial risks. The business is impacted by many factors that could affect the Company's result and financial position. It is Bioretec's strategy to identify and manage risks continuously. The most important business-related risks are associated with the group's growth targets and their achievement with the Company's chosen strategy and the sufficiency of funding to support the growth. Industry-related risks are mainly associated with a target markets which are both highly regulated and conservative and where introduction of new technologies happens slowly. Risks related to legislation, rules and regulatory compliance are associated with the group's sector of industry. Risks associated with the group's financial position mainly comprise operative currency and credit risks.

The report contains certain forward-looking information that reflects Bioretec's current views of future events and financial and operational performance. Words such as "intends", "anticipates", "expects", "can", "plans", "estimates", and similar expressions regarding indications or forecasts of future developments or trends, and which are not based on historical facts, constitute forward-looking information. Forward-looking information is inherently associated with known and unknown risks and uncertainties because it depends on future events and circumstances. Forward-looking information is not a guarantee of future results or developments and actual results may differ materially

from results referred to in forward-looking information. Forward-looking information in the report is only applicable on the date of issue of the report. Bioretec does not commit to publishing updates or revisions of any forward-looking statements as a result of new information, future events or similar circumstances other than those required by applicable legislation.

DEFINITIONS OF KEY FIGURES

Key Figure	Calculation formula
Sales margin	Revenue + other operating income - change in inventories - materials and services
Sales margin %	(Sales margin / Revenue) x 100
EBITDA	Revenue + other operating income - change in inventories - materials and services -personnel expenses - other operating expenses
EBIT	Revenue + other operating income - change in inventories - materials and services -personnel expenses - other operating expenses - depreciation and amortization
Net profit (loss)	Revenue + other operating income - change in inventories - materials and services -personnel expenses - other operating expenses - depreciation and amortization – net financial expenses - income taxes
RD 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 bank receivables	Cash and bank receivables 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)

DECLARATION

DECLARATION OF THE BOARD OF DIRECTORS AND THE CEO

The Board and the CEO assure that this interim report gives a true and fair view of the development and the Company's operations, position and results and describes significant risks and uncertainties faced by the Company

Place: Tampere

Time: 22 April 2021

Timo Lehtonen
CEO

Tomi Numminen
Chairman of the Board

Hans Moitzi
Member of the Board

Pertti Törmälä
Member of the Board

Michael Piccirillo
Member of the Board

Hans Rósen
Member of the Board

Pekka Simula
Member of the Board