

BBS-Bioactive Bone Substitutes Plc, Financial Statements Bulletin, 1 January – 31 December 2023 (unaudited)

# **Preparations for commercial phase initiated**

#### JULY-DECEMBER

- In the second half of 2023, BBS made significant progress in the CE marking process of its first product, ARTEBONE® Paste, and continued ramping up production capabilities. In November, the company received confirmation from the Notified Body that the company's quality system had received final approval, and in the same month the consultation with the Medicines Agency began.
- In October, the company appointed Juliusz Rakowski as the new CEO, and at the turn of the year other management team appointments were announced as part of the ongoing transition from research and development to the commercial phase. In the second half of the year, the company started initial commercialization measures and discussions with potential distributors.
- In November-December, the company carried out a rights issue, raising a total of approx. 1.75 million euros in net proceeds.
- The company generated no revenue during the review period.
- The financial result in the review period was EUR -1.84 (-1.42) million
- Cash flow from operations was EUR -1.49 (-1.32) million.
- Cash and cash equivalents on 31 December 2023 were EUR 1.97 (1.52) million.

#### **YEAR 2023**

- In addition to the share issue mentioned above in Nov-Dec, the company arranged a rights issue in May-June, raising a total of approx. EUR 3.1 million in net proceeds.
- The company generated no revenue during the review period.
- The financial result in the review period was EUR –3.48 (-3.09) million.
- Cash flow from operations was EUR –2.92 (-2.82) million
- Cash and cash equivalents on 31 December 2023 were EUR 1.97 (1.52) million.

The figures in the review are rounded, so the sum of the individual figures may differ from the total presented. BBS's accounting period is a calendar year. Figures in parentheses refer to the corresponding period of the previous year, unless otherwise stated. The information in the review is unaudited.

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#### OUTLOOK

## Guidance for 2024

BBS expects the authorities' decision on approving the CE marking application during the second quarter of 2024. The company expects commercial operations to begin at the end of the second half of 2024.

# **Assumptions**

Based on the currently available information, the company's view is that there are no longer product risks associated with the remaining technical phases of the regulatory approval process, as the company has met the requirements related to the product. According to the management, the main actual challenge is predicting the time required for the final phases of the official approval process, which the company cannot entirely control. The achievement of the guidance requires that the approval process proceeds without significant delays on the part of the authorities, including the final audit by the Notified Body. The company has not yet received the exact date for the audit but expects it to take place in the spring of 2024.

The company has initiated the preliminary commercialization measures for ARTEBONE® Paste and sales are expected to begin at the end of 2024. Sales are estimated to be moderate during the current year and to increase gradually during the following year.

Further measures are required to ensure the sufficiency of the company's financing in order to implement the company's plans following the expected approval of the CE marking. The company continues discussions to secure additional funding to enable the continuation of the development work as well as initiating commercial activities.

# **KEY FIGURES**

1000 EUR	7-12/2023	7-12/2022	Change, %	1-12/2023	1-12/2022
Other operating income	10	9	7.9	20	64
Personnel expenses	624	587	6.4	1,245	1,315
Depreciation and amortization	109	112	-3.0	217	225
Other operational expenses	1,065	756	40.8	1,921	1,446
Result for the period	-1,842	-1,416	30.0	-3,484	-3,093
Cash flow from operations	-1,492	-1,310	13.0	-2,923	-2,816
Change in cash position	300	1,872	-116.0	454	281
Equity ratio <sup>1)</sup> , %	48	40	20.4	48	40
Earnings per share, EUR, outstanding shares <sup>2)</sup>	-0.10	-0.15	-36.3	-0.18	-0.38
Earnings per share, EUR, diluted	-0.13	-0.4	-8.4	-0.24	-0.35
Number of shares at the end of the period (outstanding shares)	19,297,175	9,668,351	99.6	19,297,175	9,668,351
Average number of shares in the period (outstanding shares)	14,406,139	9,450,771	52.4	12,091,414	8,211,650
Equity per share, EUR 3)	0.26	0,.4	-40.1	0.26	0.44
Cash and cash equivalents	1,971	1,517	29.9	1,971	1,517
Shareholders' equity	5,108	4,271	19.6	5,108	4,271
Balance sheet total	10,613	10,688	-0.7	10,613	10,688

<sup>1)</sup> Equity ratio = Equity / (Balance sheet total – Advances received)

 <sup>2)</sup> EPS = Net Profit (Loss) / Average number of outstanding shares in the period
 3) Shareholders' Equity / Total number of outstanding shares at the end of the period

#### **CEO JULIUSZ RAKOWSKI**

During the second half of the year, BBS progressed as planned with the CE marking process. The most significant news at the end of the year was the notification from the Notified Body that the company's quality system had been approved. At the same time, we received information that the Medicines Agency's consultancy conducted by Fimea, which is essential for the final product approval, began in November 2023. Thus, I am pleased to be able to state that all the final steps of the CE marking process have been initiated. According to the company's management, approval is attainable in the second quarter of 2024.

According to our assessment, there is no longer actual product risk associated with the remaining product approval process. The company cannot control authorities' schedules, but as the approval process continues to make expected progress, we have initiated preparations for the commercial phase already in 2023.

At the turn of the year, several new members were appointed to the company's management team, adding valuable experience for both sales and production functions in the commercial phase. During the second half of the year, we continued fine-tuning production lines and processes, as well as carrying out validation batches in production.

In February 2024, after the reporting period, we took part in the prestigious American Academy of Orthopedic Surgeons exhibition in United States. Several European industrial operators, pharmaceutical companies, and distributors were also present at the event. Meetings with potential customers reinforced my confidence in the market's expectations for the product.

ARTEBONE® Paste combines bone minerals with growth factors, making it unique and as effective as using the patient's own bone graft. At the same time, the outcome for healing is better than by using minerals alone. For this reason, we believe we have the potential to displace the over 600 synthetic bone graft materials currently on the market. Once we have obtained the approval, we will finally be able to start selling the product, through which the company will move into a new phase.

As we have stated before, the approval processes for medical devices are typically lengthy, and the frustratingly slow progress of regulatory process has required patience from everyone involved. This patience will still be required in the spring. During the beginning of the year, we will continue to support the authorities in every way possible to ensure that we may receive the approvals according to the schedule. At the same time, we continue preparations for the commercial phase. The Notified Body has already submitted additional questions and requests for further information. I am pleased to say no significant non-conformities have surfaced in these inquiries.

#### **MARKETS**

Orthopaedics addresses the treatment of musculoskeletal disorders, injuries, and diseases. Orthopaedic diseases have significant impact on public health worldwide. They are the second largest cause of disability and user of resource of health care in the world. The significant factor is the rising number of surgeries caused by the ageing population and overall improvement in treatment coverage.

Approximately 1/3 of all relevant operations are made with autograft. Therefore, the potential bone graft substitute market can, based on BBS's estimates, grow by 50 % to up to 4 billion USD. When a product, that is in every way a good substitute for the autograft comes on the market, orthopaedic surgeons are known to be happy to switch from autograft to substitute, which is one of the forces driving the market forward.

At the same time, due to governments revenue loss, even greater savings objectives are put to healthcare systems. As a result, products and services that create savings without sacrificing quality of care are now in a much more competitive position, according to the company's management. ARTEBONE® Paste, developed by BBS, addresses this need.

#### Sources:

Orthoworld (The Orthopaedic Industry Annual Report 2021), Vision Research Reports (Bone Graft And Substitutes Market Size, Share, Trends, Growth, Production, Consumption, Revenue, Company Analysis and Forecast 2021–2028).

#### STRATEGY AND GOALS

The company's strategy is to commercialize the protein extract by developing bone substitute products, and to market them independently at the local markets. In other markets, the product is intended to be marketed through distributors and partners.

The company also aims to offer the protein extract to the company's partners as material for developing their own products and supports partners in their product development work and marketing.

### **Short-term strategy**

The company's short-term goal is to successfully obtain CE marking for the ARTEBONE® Paste implant during the second quarter of 2024 and initiate marketing to launch the first product. According to the company's plans, its first geographic market areas are the Nordic countries and certain other European markets. The company aims to obtain FDA approval required for entry into the US market after securing the CE marking.

#### **MAIN EVENTS DURING 2023**

During the year 2023, BBS made significant progress in the CE marking process for its first product, ARTEBONE® Paste, and continued the ramp-up of production. The company also carried out two rights issues to strengthen its financial position and initiated preparations for the commercial phase.

Regarding product classification, the company received a positive decision on 26 May, stating that ARTEBONE® Paste can be classified as a medical device. This ensured that the CE marking process for the first product could proceed according to a simpler and more cost-effective administrative process. As a result of this decision, the company became a significant precedent from a regulatory perspective in terms of how such products can be approved.

Regarding the quality system, the Notified Body conducted two audits in March (10-13 March 2023) and August (29-31 August 2023). In November (25 November 2023), the company announced that it had received a notification from the Notified Body of the final approval of the quality system and that an official quality certificate had been issued to the company.

The medicine agency's consultation with Fimea began according to information provided by the authority on 21 November 2023, and is estimated by the company to last 3-7 months.

Regarding product approval, the notified body continued reviewing the documentation provided by the company and issued additional questions and requests for further information, which did not surface any significant non-conformities. The company has supplemented its responses to the authority and anticipates that the next review by the notified body will take place in the spring of 2024.

During the second half of the year, the fine-tuning of production lines and processes continued, and production validation processes were advanced with the goal of ensuring CE marking and the ability to reliably manufacture products for the upcoming launch.

To secure the sufficiency of the company's financing, BBS carried out two rights issues during the year. More information about the rights issues can be found under the section "Share / Rights Issues."

# The product's journey towards commercialization

Phase	Action	Status
	Preclinical animal tests	Completed
Product development	Functionality and efficiency tests	Completed
	Clinical tests	Completed
	Submitting the CE application	Completed
	Quality system approval	Completed
	1st audit	Completed
	2nd audit	Completed
	Additional audit	Completed
	Additional measures	Plan approved
CE marking	Product classification	In process
	Audit	Expected in the spring 2024
	Product classification	Completed
	Consultation with the Medicines Agency	In process
	Production lines and line certification	Mostly completed
	CE marking	Expected in the second quarter of 2024
Commercialization	Preliminary launch	Initiated
Commercialization	Extensive commercialization	In preparation

#### FINANCIAL REVIEW

The review has been prepared in accordance with the Finnish Accounting Act and the rules of the First North marketplace. The review and the financials are unaudited. BBS Plc owns 100% of the shares of the subsidiary Bio Bones Ltd. Bio Bones Ltd owns and manages the Company's property in Reisjärvi. Bio Bones Ltd has no other business.

# Revenue and profitability

The company generated no revenue during the financial year. The consolidated result for the review period was EUR -3.48 million (-3.09), mainly consisting of expenses related to research and development, administration and finance.

### **Investments**

The capital expenditure on machinery and equipment at Reisjärvi production site amounted to EUR 0 (78) thousand. All the development expenses were recognized as costs in the Profit and Loss Statement.

## **Financing**

Company's operative cash flow in 2023 was EUR –2.92 million (2.82).

During the year 2023, the company raised a total of EUR 3.52 million through two rights issues. Additionally, as a result of subscriptions to the option program (TO2) associated with the 2022 rights issue, the company raised EUR 0.165 million before expenses. More information about the rights issues can be found in the "Share / Rights Issues" section.

At the end of reporting period, the company's cash and cash equivalents amounted to EUR 1.97 million. According to the estimate by the management, the available cash reserves are not sufficient for the cash expenses of the next 12 months. The company's management may influence the adequacy of funding with its decisions.

In March, BBS agreed (press release on 31 March 2023) with RiverFort Global Opportunities PCC Ltd ("RiverFort") to extend the repayment installments and deadlines for one year regarding the loan agreement announced by the company on 30 September 2021. The key commercial terms of the loan remained unchanged. The reference price for the amount of the loan in use was redefined according to the contract terms, being EUR 1.008 per share. Similarly, the fixed conversion price is EUR 1.4113 per share. BBS issued to RiverFort warrants at a price of EUR 1.4113 per share, totaling 177,140 warrants, with a subscription period ending in March 2027. During the financial year, RiverFort converted a total of EUR 0.42 million worth of RiverFort's loan capital into equity, resulting in the transfer of 958,860 shares to RiverFort, including a conversion fee. At the end of the financial year, the short-term liabilities included an unconverted portion of the loan totaling EUR 0.13 million.

#### **Balance sheet**

The balance sheet total on 31 December 2023 was EUR 10.61 (10.69) million. At the end of the review period, the short-term debts amounted to EUR 1.38 (1.70) million, out of which EUR 0.67 (0.58) million were interest bearing loans to credit institutions. The long-term interest-bearing debts amounted to EUR 3.78 (4.36) million and subordinated Capital Loan to EUR 0.18 (0.18) million. The financing costs were EUR -0.12 (-0.14) million.

No capitalized product development investments were made during the financial year.

# **Equity**

The company's total equity on 31 December 2023 was EUR 5.10 million. (31 December 2022; 4.27) The rights issue in May-June and in November considerably strengthened the equity.

#### PERSONNEL AND MANAGEMENT TEAM

At the end of the review period, the company's staff consisted of the CEO and 22 (21) employees. During the review period, one person was recruited to strengthen production resources. Of the personnel, 14 work at the factory in Reisjärvi and 8 work in Oulu.

On November 2nd, the company announced that Juliusz Rakowski has been appointed as the new CEO of the company, effective from November 3rd, 2023, as BBS prepares for the commercial phase.

On December 27, 2023, the company announced that Merja Haikola (M.Sc. Chem.) has been appointed as the Accountable Director (QP), effective from December 23, 2023.

During the publication of the report the management team of BBS consists of:

- Juliusz Rakowski, CEO, as of 3 November 2023, Ilkka Kangasniemi until 2 November 2023
- Jari Kortesluoma, CFO
- Jussi Jukka, Production Manager until 29 December 2023, Kimmo Tyni as of 15 January 2024
- Merja Haikola Director of Quality, Accauntable Director (QP) as of 27 December 2023, Soile Hakala until 27 December 2023
- Mikko Viitanen, Director of Quality Control

#### **GOVERNANCE**

## **Annual General Meeting (AGM) 2023**

The AMG was held on Friday, March 30, 2023, in Oulu.

The AGM confirmed the financial statements for the financial year 2022, discharged the Board of Directors and the CEO from liability. The AGM decided that the company will not pay dividends for the financial year 2022.

The AGM decided that the number of Board members will be five (5). Jarmo Halonen, Pekka Jalovaara, Seppo Nevalainen, Kirk Andriano, and Ahti Paananen were elected as board members for the term ending at the close of the next AGM. The AGM decided that the chairman of the board be paid EUR 1,500 per meeting and EUR 1000 per meeting for other members. No compensation will be paid for e-mail meetings.

Ernst & Young Oy was re-elected as the company's auditor, and Jari Karppinen, KHT, will act as the company's principal auditor. The auditor is paid a fee according to a reasonable invoice approved by the company.

The AGM decided to authorize the board of directors to decide in one or more installments on share issues and on the issue of option rights and other special rights entitling to shares referred to in Chapter 10, Section 1 of the Limited Liability Companies Act, as follows:

The maximum number of shares to be issued pursuant to the authorization shall not exceed 6,000,000 shares. The Board of Directors decides on all terms and conditions for issuing shares, options and other special rights entitling to shares. Share issues and the issuance of option rights and other special rights entitling to shares may take place in deviation from the shareholders' pre-emptive subscription right (directed issue) if there is a weighty financial reason for the company to do so. The authorization applies to the transfer of both new shares and own shares held by the company. In the company's share issue, shares may be transferred either in exchange for payment or free of charge. A directed share issue may be free of charge only if there is a particularly significant financial reason for the company and it is in the interests of all its shareholders. The authorization is valid until 30 June 2024, and it revokes the authorization granted by the Annual General Meeting on 17 March 2022, as it enters into force.

The minutes of the AGM can be viewed on the website of BBS-Bioactive Bone Substitutes Plc at www.bbs-artebone.fi.

## Extraordinary general meeting (EGM) 2023

The EGM was held on Thursday, October 23 2023, in Oulu.

The Extraordinary General Meeting authorized the Board of Directors to decide in one or more instalments on share issues and on the issuance of option rights and other special rights entitling to shares referred to in Chapter 10, Section 1 of the Finnish Limited Liability Companies Act as follows: The maximum number of shares to be issued pursuant to the authorization shall not exceed 7,000,000 shares. The Board of Directors decides on all terms and conditions for issuing shares, options and other special rights entitling to shares. Share issues and the issuance of option rights and other special rights entitling to shares may take place in deviation from the shareholders' pre-emptive subscription right (directed issue) if there is a weighty financial reason for the company to do so. The authorization applies to the transfer of both new shares and own shares held by the company. In the company's share issue, shares may be transferred either in exchange for payment or free of charge. A directed share issue may be free of charge only if there is a particularly significant financial reason for the company and it is in the interests of all its shareholders. The authorization is valid until 23 October 2027 and it revokes the authorization granted by the Annual General Meeting on 30 March 2023 as it enters into force.

The minutes of the general meeting can be viewed on the website of BBS-Bioactive Bone Substitutes Plc at www.bbs-artebone.fi.

## **SHARE**

### Shares and share capital

The market capitalisation of BBS at the end of the review period on 31 December 2023 was EUR 9.5 million. The closing share price on 29 December 2023 was EUR 0.49. The highest closing price per share of the review period was EUR 1.11 and the lowest was EUR 0.38.

According to Euroclear's shareholder register, BBS had 4,839 (4236) shareholders on 31 December 2023. At the end of the financial year, there were a total of 19,297,175 (previously 10,177,874) registered shares, of which the company held 0 (previously 509,523) shares in treasury. Following the reporting period, the company announced (January 31, 2024) that it had conducted a directed share issue. After this, BBS holds a total of 1,000,000 of its own shares, equivalent to 4.9 percent of the company's shares.

On 31 December, 2023, BBS's board of directors held a total of 1,282,445 shares (31 December 2022: 1 134,539), including shares owned through controlled companies, i.e. 6.65 % (11.7 %) of the total number of outstanding shares. At the end of the reporting period, the CEO held 25,000 shares of the company's stock. Information about the company's insiders' trading in the company's shares is published on the company's website.

#### **Shareholders**

Below is a list of the company's largest shareholders at the end of the reporting period.

	31 December 2023		31 Decemb	per 2022
	Number of shares	% of outstading shares	Number of shares	% of outstading shares
Reisjärven Kunta	2,677,716	13.9 %	1,051,081	10.9 %
Finha Capital Oy	2,357,965	12.2 %	1,408,404	14.6 %
Panvest Oy	1,304,590	6.8 %	476,838	4.9 %
Jalovaara Pekka <sup>(1</sup>	654,050	3.4 %	568,025	5.9 %
Paananen Ahti <sup>(1</sup>	520,904	2.7 %	520,904	5.4 %
Halonen Jukka	281,594	1.5 %	226,481	2.3 %
Halonen Veronika	254,369	1.3 %	229,309	2.4 %
Rosenqvist Alexandra	253,971	1.3 %	230,309	2.4 %
Nordnet Bank AB, nominee registered	225,050	1.2 %	18,629	0.2 %
Skandinaviska Enskilda Banken AB,no.reg.	210,846	1.1 %	87,970	0.9 %
10 largest	8,741,055	45.3 %	4,817,990	49.8 %
Others	10,556,120	54.7 %	4,850,036	50.2 %
Total	19,297,175	100.0 %	9,668,026	100.0 %
BBS-Bioactive Bone Substitutes	0		509,523	
Total	19,297,175		10,177,549	

<sup>&</sup>lt;sup>1)</sup> Ahti Paananen and Pekka Jalovaara are members of the company's board.

#### **Rights Issue June 2023**

On June 5, 2023, the company announced that the board had decided to organize a rights offering totalling approximately EUR 2.9 million. The subscription period for the share issue began in Finland and Sweden on June 12, 2023, ending on June 26, 2023, in Sweden and on June 28, 2023, in Finland. The results of the offering were announced after the reporting period on July 3, 2023.

The share issue was subscribed to 62.8 percent, and the company raised approximately EUR 1.84 million in gross proceeds from the share issue before deducting expenses and fees incurred from the share issue. Taking into account the expenses and fees, the company received approximately EUR 1.77 million in net proceeds from the share issue.

As the subscription price for the shares with the 2022 warrants (TO2) was higher than the subscription price used in the rights issue decided by the board on June 5, 2023, and because investors who

subscribed for shares with the 2022 warrants (TO2) could not participate in the share issue with the new shares subscribed with the 2022 warrants (TO2) due to the timing of the share issue, the board considered that ensuring equal treatment of shareholders constitutes a particularly compelling financial reason for the company to issue shares without consideration, taking into account the company's interests and the interests of all its shareholders. The number of shares allocated to each investor was calculated so that one (1) share was issued for every five (5) shares subscribed with the 2022 warrants (TO2). As a result of the free issue, the company transferred a total of 50,663 of its own shares.

The shares subscribed for in the share issue were registered in the trade register on July 10, 2023. Trading in the shares began on the First North Growth Market Finland on July 11, 2023. As a result of the share issue, including the TO2 warrants and the free issue, the total number of BBS shares increased by 3,940,973 shares. After the share issue, the total number of the company's shares was 14,118,847.

# **Rights Issue December 2023**

On November 20, 2023, the company announced that the board had decided to organize a rights issue of up to approximately EUR 2.63 million. The subscription period for the share issue began in Finland on November 27, 2023, and ended on December 13, 2023. The results of the offering were announced on December 18, 2023.

The share issue was subscribed to 71.1 percent, and the company raised approximately EUR 1.87 million in gross proceeds from the share issue before deducting expenses and fees incurred from the share issue. Taking into account the expenses and fees, the company received approximately EUR 1.75 million in net proceeds from the share issue.

The shares subscribed for in the share issue were registered in the trade register on December 22, 2023. Trading in the shares began on the First North Growth Market Finland on December 27, 2023. As a result of the share issue, the number of BBS shares increased by 4,678,328 shares. After the share issue, the total number of the company's shares is 19,297,175.

## **Authorizations**

The extraordinary general meeting of the company decided on March 30, 2023, to authorize the board to decide on one or more share issues as well as the granting of option rights and other special rights entitling to shares referred to in Chapter 10, Section 1 of the Finnish Companies Act as follows: The maximum number of shares to be issued under the authorization may be up to 6,000,000 shares. After the rights issue in June, the company has approximately 2,313,607 remaining authorizations. The authorization is valid until June 30, 2024.

The extraordinary general meeting of the company decided on October 23, 2023, to authorize the board to decide on the issuance share issues as well as the issuance of option rights and other special rights entitling to shares referred to in Chapter 10, Section 1 of the Finnish Companies Act as follows: The maximum number of shares to be issued under the authorization may be up to 7,000,000 shares. After the rights issue in December, the company has approximately 2,321,672 remaining authorizations. The authorization is valid until October 23, 2027.

### Directed share issue to the company itself

During its meeting on September 3, 2023, the company's board decided on a total of 500,000 shares in a free share issue to the company itself. The issuance is intended to prepare for potential conversion of loan capital and other possible actions within the framework of the authorizations

granted by the extraordinary general meeting on March 30, 2023. Following the directed share issue, BBS holds a total of 601,451 of its own shares, equivalent to 4.1 percent of the company's shares.

## **Share-based incentive system**

The company has a valid option program from 2012, approved by the general meeting on July 18, 2012. Authorized by the general meeting, the board decided on the options on January 2, 2013. Options have been granted to key personnel of the company, and each option can be exercised to subscribe for one share at a price of one euro per share until December 31, 2023. In its meeting on November 20, 2023, the board decided to extend the exercise period of the option program until the end of 2029 and for a small portion until the end of 2025.

The exercise of options may result in a maximum of 170,000 new shares, and thus this program does not have a significant impact on the earnings per share ratio.

## Withdrawal of the dual listing

The company's board decided on February 13, 2023, to withdraw its dual listing on Nasdaq First North Growth Market Sweden. In making this decision, the board took into account the low trading volumes of BBS shares after the company's initial public offering in 2018, as well as the small number of shareholders registered with Euroclear Sweden AB. The board also assessed the additional costs to the company and the administrative responsibilities associated with compliance with listing requirements related to the dual listing. On February 16, 2023, Nasdaq Stockholm AB approved the application. The last trading day for BBS shares on Nasdaq First North Growth Market Sweden was March 3, 2023.

# Flagging notifications

The company did not receive flagging notifications in accordance with Chapter 9, Section 5 of the Securities Market Act during the reporting period.

#### **RISKS AND UNCERTAINTIES**

This section describes the most important risks related to the company's operations. According to the management's view, there have been no significant changes in the risks and uncertainties related to the company operations since the half-year review, apart from the increases in average application processing times. The risks related to the company's operations are described in more detail in the prospectus of the November 2023 rights issue, which can be found on the company's website at <a href="https://www.bbs-artebone.fi/investors/share-issue-2023-11/">https://www.bbs-artebone.fi/investors/share-issue-2023-11/</a>.

### Risks related to obtaining the CE marking

The submission of the CE marking application to the authorities in 2022 significantly reduced the company's perceived risks regarding the commercialization of its first product. As the regulatory process progresses, risks gradually decrease, but there are several essential risks associated with the process. During the authorities' inspections, deficiencies may be identified in the application, or correction and supplementation requirements may be requested. Implementing these requirements may pose unexpected internal challenges for the company, or its service providers may face difficulties in delivering the required solutions on time. There may also be delays in regulatory cooperation beyond the company's control. Based on the currently available information, the company's view is that there is no product risk associated with the remaining final technical stages of

the licensing process, as the company has met the product-related requirements. The main challenge, according to management, is predicting the time it will take to complete the final stages of the regulatory process, which the company cannot entirely control. Since 2022, public reports have indicated significant congestion in the regulatory process. After obtaining the CE marking, there may be restrictions on clinical use areas approved in the EU compared to the applied-for use area. After obtaining the CE marking, product development risks decrease for the company's first product, and the remaining essential risks are related to the success of further clinical trials.

## Risks related to financing

The company's financing involves risks in the short and long term. The partial realization of the share issue (62.8% and 71.7%) has affected the adequacy of the company's financing. In addition, financial market instability can make it difficult to acquire further financing. The uncertainty in the stock market caused by the war in Ukraine is still considered acute risk. The tightening global atmosphere in the Middle East and around Taiwan could quickly complicate access to financing in the near future. The available cash reserves are not sufficient for the cash expenses of the next 12 months. The company's management can influence the adequacy of funding with its decisions.

## Risks related to personnel

Operational risks include, among other things, dependence on the competence of key personnel and measures to engage them.

### Risks related to the development of medical devices

As a product development and manufacturing company for medical devices, BBS is a long-term investment target. The development phase is long, and it is followed by a marketing and sales growth phase lasting four to five years after the launch. When the turnover has become positive, the growth phase typically continues with the same product for a long time

# **EVENTS AFTER PERIOD-END**

On January 2, 2024, the company announced that Kimmo Tyni has been appointed as the Production Director of BBS-Bioactive Bone Substitutes Oyi, starting from January 15, 2024.

On January 31, 2024, the company's board decided on a free share issue of 1,000,000 shares to the company itself. The issuance is intended to prepare for potential conversion of loan capital and other possible measures within the framework of the authorizations granted by the extraordinary general meeting on October 23, 2023. After the directed share issue, BBS holds a total of 1,000,000 of its own shares, representing 4.9 percent of the company's shares thereafter.

On February 21, 2024,the company announced that it has agreed to draw down an instalment of EUR 500,000 with RiverFort Global Opportunities PCC Ltd ("RiverFort") in accordance with the terms of the financing agreement announced on September 30, 2021. BBS will pay a transaction fee of EUR 45,000 by transferring 74,915 of its own shares to RiverFort at a price of EUR 0.6007 per share. The reference price is, according to the original financing agreement, tied to the average share price over the five (5) trading days preceding the payment of each instalment (VWAP). After the drawdown, BBS will issue 416,195 warrants to RiverFort (with an exercise price of EUR 0.8410 per share, 140% of the reference price) with a validity period of 48 months. After the transfers, BBS will have in total of 925 085 treasury shares.

### **FINANCIAL CALENDAR FOR 2024**

- Financial Statements Release for the year 2023 will be published on 26 February 2024
- The Annual Report for the year 2023 will be published during the week 13/2024 at the latest.
- The Annual General Meeting is planned to be held on 30 April 2024
- Half-year financial report January-June 2024 will be published on 30 August 2024

The company's previously published reports can be found on the BBS investor website at: https://www.bbs-artebone.fi/investors/financial-reports/.

26 February 2024
BBS-Bioactive Bone Substitutes Plc
Board of Directors

DISTRIBUTION
Nasdaq Helsinki
https://www.bbs-artebone.fi/

#### **BBS** in brief

BBS -Bioactive Bone Substitutes Plc is a orthobiology company that started its operations in 2003. We have developed a new product for the treatment of complex bone fractures and bone healing issues. Our goal is to provide next-generation medical products for the treatment of bone injuries in orthopedic surgery. In the pharmaceutical industry, the development and research work require perseverance and courage to innovate. We have a track record of over 20 years in this field. Our company is characterized by expertise, innovation, and dedicated employees who are passionate about their work. Our first developed product, ARTEBONE® Paste, is in the final stages of the CE marking process to enable its commercialization in the EU market. We are based in Oulu with a medical manufacturing facility in Reisjärvi, holding a manufacturing license. The company's headquarters are in Oulu, and we employ over 20 people.

BBS has been listed on Nasdaq First North Growth Market Finland since February 2018.

# **KEY FINANCIALS 1.1.2023 - 31.12.2023**

# **GROUP INCOME STATEMENT**

_1000 EUR	1 July. 2023 - 31 Dec.2023 <sup>1)</sup>	1 July. 2022 -31 Dec.2022	1 Jan. 2023 – 31 Dec. 2023 <sup>1)</sup>	1 Jan. 2022- 31 Dec. 2022
NET TURNOVER				
Other operating income	10	9	20	64
Materials and services total	-5	-25	-4	-30
Personnel expenses	-624	-587	-1,245	-1,315
Depreciations	-109	-112	-217	-225
Other operating expenses	-1,065	-756	-1,921	-1,446
EBIT	-1,792	-1,471	-3,367	-2,952
Financial income and expenses	-49	54	-117	-141
		4 440		
PROFIT(LOSS) BEFORE EXTRAORDINARY ITEMS	-1,842	-1,416	-3,484	-3,093
	4 040	4 446	2 494	2 002
PROFIT(LOSS) FOR THE FINANCIAL YEAR	-1,842	-1,416	-3,484	-3,093

<sup>1)</sup> unaudited

# **GROUP BALANCE SHEET**

1000 EUR		31 Dec. 2023 <sup>1)</sup>	31 Dec. 2022
ASSETS			
	NON-CURRENT ASSETS		
	Intangible assets	7,694	7,747
	Tangible assets	901	1,024
	NON-CURRENT ASSETS TOTAL	8,595	8,771
	CURRENT ASSETS		
	Debtors total	48	400
	Cash and cash equilevants	1,971	1,517
	CURRENT ASSETS TOTAL	2,019	1,917
ASSETS TOTAL		10,613	10,688
	-		
LIABILITIES			
	CAPITAL AND RESERVES		
	Share capital	80	80
	Share premium account	1,395	1,395
	Invested unrestricted equity fund	23,746	21,425
	Retained earnings (loss)	-18,629	-15,536
	Profit (loss) for the financial year	-3,484	-3,093
	CAPITAL AND RESERVES TOTAL	5,108	4,271
	CREDITORS		
	Long term loans	4,128	4,715
	Short term loans	1,377	1,701
	CREDITORS TOTAL	5,505	6,417
	CREDITORO TOTAL		
LIABILITIES TO	TAL	10,613	10,688

<sup>1)</sup> unaudited

CONSOLIDATED CASH FLOW	1 July.2023- 31 Dec.2023 <sup>1)</sup>	1 July.2022- 31 Dec.2022	1 July.2023- 31 Dec.2023 <sup>1)</sup>	1 July.2022- 31 Dec.2022
1000 EUR				
Cash flow from business operations				
Profit (loss) before extraordinary items	-1,842	-1,417	-3,484	-3,093
Adjustments				
Scheduled depreciation and amortisation	109	112	217	225
Financial income and expenses	49	-54	117	141
Other adjustments				
Cash flow before changes in working capital	-1,664	-1,359	-3,130	-2,726
Change in working capital				
Changes in short-term non-interest bearing (+) (-)	285	-26	292	-48
Changes in inventory increase (-)/Decrease (+) Changes in short-term non-interest-bearing loans Increase (+)/Decrease (-)	-48	-12	7	83
Changes in long-term non-interest-bearing loans Increase-(+)/Decrease (-)				
Cash flow from business operations before financial items and taxes	-1,427	-1,397	-2,831	-2,691
Interest paid and other financial expenses from business operations	-65	77	-92	-125
Interest received and other financial income from business operations				
Cash flow before extraordinary items and taxes	-1,491	-1,320	-2,923	-2,816
Cash flow from business operations (A)	-1,491	-1,320	-2,923	-2,816
Cash flow from investments	0	-29	0	-78
Investments in tangible and intagible goods	O	-29	O .	-70
Investments in subsidiary shares				
Loans granted	0	-29	0	-78
Cash flow from investments (B)	· ·	-23		-70
Cash flow from financing	0.040	040	0.000	0.700
Share issue	2,249	213	3,880	3,708
Riverfort Financial Arrangement		-200	0	50
Raised long-term loans	457	507	500	500
Repayment of long-term loans	-457	-537	-503	-583
Raised short-term loans				
Repayment of short-term loans	4 =04	F0.4	0.077	
Cash flow from financing (C)	1,791	-524	3,377	3,175
Changes in funds (A+B+C) Increase (+) / Decrease (-)	300	-1872	454	281
Funds at the beginning of the financial period	1,671	3,390	1,517	1,236
Funds at the end of the financial period	1,971	1,517	1,971	1,517

<sup>1)</sup>unaudited

# **CHANGES IN GROUP EQUITY**

# BBS-Bioactive Bone Substitutes Plc

(Unaudited)

		Share premium		Accumulated	
1000 EUR	Share capital	account	Share issue	profits	Equity, total
Equity 1 January 2023	80	1,395	21,425	-18,629	4,271
Profit/loss for the financial year				-3,484	
Share issue			4,321		
Equity at 31 December 2023	80	1,395	25,746	-22,113	5,108
Equity at 1 January 2022	80	1,395	17,695	-15,536	3,634
Profit/loss for the financial year				-3,093	
Share issue			3,730		
Equity at 31 December 2022	80	1,395	21,425	-18,629	4,271
Equity at 1 January 2021	80	1,395	17,377	-12,765	6,087
Profit/loss for the financial year				-2,771	
Share issue			318		
Equity at 31 December 2021	80	1,395	17,695	-15,536	3,634