# BBS-Bioactive Bone Substitutes Plc: Financial Statements Review 1.1.-31.12.2021 (unaudited)

Financial statement release on February 24th 2022 at 12:00 (CET)

BBS- Bioactive Bone Substitutes Plc's ("BBS", "the Company") Financial Statements Review 1.1.-31.12.2021 (unaudited)

#### Year 2021 in brief (Reference period 2020)

- In 2021, the company has continued to prepare its first product, Artebone® Paste CE marking application, and to level the production and quality system with regulatory requirements.
- The company has invested significantly in production and quality assurance equipment and facilities and has recruited additional personnel for production and quality in accordance with the requirements of the CE marking process.
- The new MDR regulatory requirements have been responded to by producing a significant amount of new documentation during the year.
- The production process claims of the BBS patent application 'A METHOD FOR PREPARING A BONE PROTEIN PREPARATION AND A BONE PROTEIN PREPARATION' were accepted in the USA.
- The final report of the animal test required by the authorities was received in September 2021. The results of the experiment confirm the functionality of Artebone® Paste, which contains reindeer bone protein extract, and will make it possible for the company to respond positively to the demands made by the authorities.
- BBS had no sales revenue during the financial year 2021.
- Cash flow from operating activities was EUR –2,52 (-2,42) million.
- BBS's cash and cash equivalents on December 31<sup>st</sup>, 2021 were EUR 1,24 (3,44) million.
- In order to secure the working capital BBS-entered into an investment agreement with RiverFort Global Opportunities PCC Ltd for a capital facility of up to EUR 2,0 million with an initial advance of EUR 750 thousand at the end of September.
- On the same occasion 410,000 shares without consideration were issued to the Company itself for the payment of the RiverFort implementation fee, for potential loan conversions as well as for other possible purposes based on Authorisation given by the AGM April 28th 2021.

# **Key Figures Group**

1 000 €	1.1-31.12.2021	1.1-31.12.2020
Other operating income	58	46
Personnel expenses	1 199	795
Depreciation and	231	
Amortisation		214
Other operating expenses	1 144	1 599
Profit /Loss for the period	-2 771	-2 731
The Cash Flow from Business Operations	-2 520	-2 418
Change in Cash Position	-2 202	2 923

Equity ratio %	35 %	48 %
Earnings per share, EPS €	-0,42	-0,46
Earnings per share €, diluted	-0,41	-0,45
Number of shares at the end of	6 847 520	6 571 525
period (BBS)		
Average number of shares	6 606 215	5 897 533
during the period		

1 000 €	31.12.2021	31.12.2020
Cash and cash equivalents	1 236	3 438
Own capital	3 634	6 087
Balance sheet total	10 506	12 692

* Equity Ratio=	Equity
	(Balance Sheet Total – Advances Received)
* <i>EPS</i> =	Profit(Loss)
_	Average number of Shares during the Period

#### Board of Directors outlook and guidance for 2022

- The company's goal is to have the CE marking application submitted to the authorities during the current spring.
- The regulatory process is expected to progress during the year so that the timetable for the completion of process will be clarified towards the end of the year.
- Recruitment and training of product development and production personnel will continue.
- Preparations for commercial operations will begin in autumn 2022. The company initiates sales and marketing measures once the interim responses to the CE marking process from the authorities have been sufficiently positive.
- The recruitment of marketing staff is being prepared.
- Preparations for the FDA permit application will continue.
- No significant sales revenue are expected for the current year.

The company's medium-term goals have not changed. The company's expectations are

• generate significant growth in sales as a result of a two-year marketing period

- become profitable in four years from launch
- launch the product in the USA as well as in several other countries
- develop new products
- achieve partner agreements with market leaders in the field

The company's working capital will not cover the financial needs of the CE approval process and the commencement of the commercial activities . Since spring 2021 the company has taken actions to secure its finance, including the EUR 2 million financial arrangement with Riverfort Global Opportunities PCC Ltd. The company's financial resources at end of the financial period were EUR 1,2 million . After the end of the financial period, the working capital been has strengthened the by EUR 250 thousand by raising the second advance of the Riverfort arrangement and by signing a EUR 450 thousand loan commitment with Finha Capital Oy . The current working capital available is expected to cover the operative financial needs until the beginning of the second half of FY 2022. Furthermore the Riverfort arrangement enables the raising of furher EUR 1 million with approval of the lender for each advance.

The company estimates that the operative expenses for the next 12 months will be EUR 2,5-2,8 million. Additionally the financial expenses and loan repayments will reach EUR 0,7 million. Furthermore the company reserves EUR 0,5 million for the investments in product and process development and production . The amount of investments and expenses depend on the management decisions.

To secure the operations, the company is preparing a share issue and calling an extraordinary shareholders meeting to decide on the matter to conveine on March 17th 2022. The company believes to raise the sufficient funds with the share issue.

Invitation to the Meeting will be published today in connection with the Release of the unaudited Financial Statements for FY 2021.

#### FINANCIAL REVIEW

#### **Business overview**

BBS-Bioactive Bone Substitutes Plc ("BBS", "The Company") is a biomedical technology company that develops, manufactures and commercializes innovative, bioactive medical devices and implants for orthopaedic surgery. The company's administration and quality control laboratory are located in Oulu and a production facility in Reisjärvi. The company is listed on Nasdaq First North Growth Market, operated in Finland by Nasdaq Helsinki Ltd (BONEH) and in Sweden by Nasdaq Stockholm (BONES).

In 2021, the company has continued to prepare its first product, Artebone® Paste, CE marking application, and to level the production and quality system with regulatory requirements. The company has invested significantly in production and quality assurance equipment and facilities and has hired additional personnel for production and quality. Staff training has been invested in ensuring the compliance of quality system operations and production processes.

The new MDR regulatory requirements have been responded to by producing a significant amount of new documentation during the year.

BBS's patent application "A METHOD FOR PREPARING A BONE PROTEIN PREPARATION AND A BONE PROTEIN PREPARATION" production claims were approved in USA.

The final report of the animal test required by the authorities was received in September 2021. The results of the experiment confirm the functionality of Artebone® Paste, which contains reindeer bone protein extract, and make it possible for the company to respond positively to the demands made by the authorities. According to the final report, Artebone® Paste causes the bone to heal faster than the control (ceramic and extract alone).

The animal test was carried out at the request of the authorities to supplement the documentation of the CE marking application. The aim of the experiment was to demonstrate that Artebone® Paste can be classified as a medical device and that its efficacy is at an acceptable level.

The company's management previously estimated that the Company will receive a CE marking for the ARTEBONE® product it has developed to repair bone fractures and bone damage during 2021. The timetable had to be revised three times during the year due to problems caused by equipment renewal, repair needs and delays caused by service providers and suppliers. By the end of the year, most of the causes of the delays have been eliminated. The introduction of the new Medical Devices Regulation (MDR), which is under way in Europe, has increased new regulatory guidelines to be followed during the year, which has contributed to further changes to existing documentation.

In general terms, the Covid-19 pandemic has caused delays and made the operating environment more difficult.

With regard to the submission of a marketing authorisation application to the U.S. regulatory authority (FDA) targeting the local market, the measures have not progressed significantly during the fiscal year. The company expects to continue preparing an application for the FDA following the submission of the CE-marking application to the European market.

#### FINANCIAL OVERVIEW

**Operating result and R&D expenses** 

BBS Plc had no revenue during the financial year 2021, nor in the corresponding period of the previous year. The consolidated result for the review period was EUR -2,77 million (EUR -2,73 million in 2020) consisting of expenses for research and development, administration and finance.

#### **Investments and Financing**

The capital expenditure on machinery and equipment at Reisjärvi production site amounted to EUR 125 thousand (EUR 82 thousand in 2020). All the development expenses were recognised as costs in the Profit and Loss statement.

The Company's cash resources at December 31st 2021 were EUR 1,24 million (EUR 3,44 million in 2020) and decreased by EUR 2,2 million during the period (as increased by EUR 2,92 million in 2020)

In order to secure the working capital BBS-entered into an investment agreement with RiverFort Global Opportunities PCC Ltd for a capital facility of up to EUR 2,0 million with an initial advance of EUR 750 thousand The facility enables the Company to request further capital advances up to EUR 1,25 million.

#### **Acquisitions and Share Issues**

There were no mergers or acquisitions during the financial year.

On September 30th 2021 the Company's Board of Directors decided to issue 410,000 shares without consideration to the Company itself based on the authorisation by the Annual General Shareholders Meeting on April 28th 2021. The amount corresponds to approximately 6% of the company's shares. The treasury shares were aimed for payment of the implementation fee of the Riverfort financial arrangement, potential loan conversions as well as for other possible purposes in accordance with the autorisation by the AMG on April 28th 2021.

The first EUR 250 thousand of Riverfort Global Opportunities PCC Ltd's capital facility was converted into shares in November at a subscription price of EUR 1,8656 per share. The Conversion price according to the terms and conditions was based on the "90% of the lowest volume weighted average price of a trading day during ten trading days before the applicable subscription notice"-option. The conversion was executed by transferring a total of 134.005 of treasury shares to Riverfort Global Opportunities PCC Ltd. Another 32 359 units of treasury shares were transferred to settle the fee for the Initial Advance iat the price of EUR 2.086 per share.

As the share issue was registered on October 6th 2021, the total number of the company's shares was increased to 6 981 525. After the transfers, there were 243 636 treasury shares left, representing a 3.5% share of the total.

#### **Balance sheet**

The balance sheet total on December 31st 2021 was EUR 10,51 million (EUR 12,69 million in 2020). At the end of the review period the interest-bearing debts to financial institutions amounted to EUR 6,21 million (EUR 6,01 million in 2020), out of which - including the EUR 0,50 million arrangement with Riverfort - EUR 1,08 million (0,31) were due in 12 months and EUR 2,40 million (2,14) after five years or later.

The long-term interest-bearing debts include a subordinated Capital Loan worth EUR 0,176 million (0,176). The financing costs were EUR -0,20 million (-0,085) million in 2020).

During December 2021 the Company renegotiated the repayment plans for development and working capital loans worth EUR 578 680, 1 434 386 and, 2 732 000. According to the renewed agreements the loan repayment periods were extended and the repayment of EUR 578,680 were postponed for two years starting in June 2024. The arrangement will reduce the burden of outbound financial cashflow in the coming few years

During the review period no further development costs were recognised as investments into the balance sheet.

#### **The Capital Loans and Accrued Interest**

The company has a Capital Loan of EUR 175 825,46 pursuant to Chapter 12 of the Limited Liabilities Company Act.

The Loan will be paid back in equal instalments in three years starting in year 2009, if conditions are met. The interest on Loan is one percentage unit lower than the basic interest rate currently in force, however at least three percent. If payment conditions are not met, the interest will be postponed for payment to the first annual closing meeting the conditions.

At the end of the financial year the accrued interest not recognised as expense was EUR 91 087,35.

# **Equity**

The Company's equity on December 31st 2021 was EUR 3,63 million. At closing of the financial year 2020 the equity amounted to EUR 6,10 million. During the review period of 2021 the conversion of 166 364 treasury shares increased the equity by EUR 0,32 million.

The losses of the financial year were EUR -2,77 million. (EUR -2,73 million in 2020)

#### Staff, management and administration

At the end of the financial period 2021 the company employed the Managing Director and 20 staff members (16 in 2020) . Four new professionals were recruited as production resources were

strengthened. 15 members of the staff work in the Reisjärvi production site and another six are placed in Oulu. The average number of personnel during the year was 19 (12 in 2020)

Chairman of the Board Jarmo Halonen, Mr.Pekka Jalovaara and Mr.Seppo Nevalainen belonged to the BBS Board of Directors for the whole review period. Mr. Tomi Numminen left his seat at the Annual Shareholders Meeting on April 28th as Mr.Kirk Andriano was appointed as a new member. There are two independent members in the BBS Board.

The BBS Management consisted of the Managing Director Ilkka Kangasniemi, COO Hanna Tölli, The Quality and Assurance Manager Soile Hakala and The Manager of Quality Control Laboratory Mikko Viitanen. CFO Liisa Hukka joined the Management Team on February 1st as previous CFO Hannu Säynäjäkangas retired.

Ernst&Young Oy, Authorised Public Accountants, acted as the auditor of the company having Mr. Jari Karppinen (Auditor certified by the Central Chamber of Commerce) as the auditor with principal responsibility.

#### **Annual General Meeting (AGM) 2021**

BBS's AGM was held on April 28th 2021 in Oulu. The AGM approved the financial statements for the financial year 2020 and discharged the members of the Board of Directors and the CEO from liability. The AGM decided in accordance with the proposal by the Board of Directors, that no dividend is paid for the financial year January 1st 2020 - 31 December 2020, and that the loss for the financial year is recognised in the profit/loss account.

The AGM decided that the number of Board members will be four (4). The AGM approved the remuneration of the Board of Directors as follows: The Chairman will be paid EUR 1300 per meeting and the other members EUR 900 each. No compensation on e-meetings will be paid. Additionally the Company will compensate reasonable travel expenses according to the Company's travel policy. Ernst&Young Oy, Authorised Public Accountants, was re-elected as the auditor of the Company having Mr. Jari Karppinen (Auditor certified by the Central Chamber of Commerce) as the auditor with principal responsibility.

### **Share-based incentive plan**

The company has an option program approved by the AGM on July 18th 2012. The Board of Directors decided on options on January 2nd 2013 as authorised by the AGM. Last options were allocated to the key personnel in 2013. Each option entitles its holder to subscribe for one share at the price of one euro during the subscription period for ordinary shares, which started April 9th 2013., On January 9th 2018 the Board of Directors extended the subscription period until December 31st 2023. As the

number of new shares in the option program is limited to 170 000 representing only 2,4% of the total, this has no perceptible impact on the earnings or other key figures per share

#### **Valid Authorisations by AGM**

The Annual General Meeting on April 28th 2021 authorised the Board of Directors to decide on a share issue which may be carried out by increasing the share capital by a new subscription or by taking out convertible bonds in one or more tranches. The right to a directed share issue is not restricted. The authorisation includes the right to deviate from the shareholders' pre-emptive right under the Companies Act to subscribe for new shares or convertible bonds, as well as the right to decide on subscription prices, those entitled to subscribe and subscription terms. The share subscription price will be recorded in the invested unrestricted equity fund.

The authorisation may be used against the shareholders pre-emptive rights if there is a compelling financial reason for the company, such as the expansion of the company's shareholder base or other arrangement related to the development of the company's business, an incentive program or arrangements in the capital management. Pursuant to the authorisation, shares may also be offered to members of the company's related parties, but not for the benefit of the related parties, deviating from the shareholders' pre-emptive subscription right. The Board of Directors has the right to decide that the shares may be given as subscription in kind, using the right of set off, or other specific conditions. The total number of the authorisations were 3 000 000 ( three million ) representing approximately 45% of the company's share capital

The authorisation is in force until the next Annual General Meeting, however no longer than until the June 30th 2022.

Authorisations worth 410 000 shares were used in October as the company issued the shares for its own possession. The amount of valid authorisations is 2 590 000 representing 37% of the total.

#### Risks and uncertainties

Significant risks and uncertainties independent of the Company are identified both in the area of the product development and the commercialising activities. Risks can lead to further postponement, as the authorities have the right to require complements and alterations to the documentation presented. The risk in the product classification lies in the interpretation of the authorities. The decision will be based on the results of the animal testing, which are available.

The FDA registration process has been postponed. The matters causing delays in the CE application process have reflected the FDA registration. I

Operational risks include, among other things, the dependence on the skills of the key personnel and the measures to strengthen their commitment.

On the financial side, the uncertainty in the stock market caused by the Covid19 pandemic is considered a risk. However, as a medical device development and manufacturing company, BBS is more of a long-term investment. The initial R&D phase takes a long time, followed by four to five years of post-launch marketing and growth of sales. Once sales have become profitable, the growth phase with the same product potentially continues for a long period of time.

#### **Working Capital**

At the moment the working capital available will not cover the financial needs of the CE approval process and the commencement of the commercial activities. Since spring 2021 the company has taken actions to secure its finance, including the EUR 2 million financial arrangement with Riverfort Global Opportunities PCC Ltd. The company's financial resources at end of the financial period were EUR 1,2 million. After the end of the financial period, the working capital been has strengthened the by EUR 250 thousand by raising the second advance of the Riverfort arrangement and by signing a EUR 450 thousand loan commitment with Finha Capital Oy. The current working capital available is expected to cover the operative financial needs until the beginning of the second half of FY 2022. Furthermore the Riverfort arrangement enables the raising of furher EUR 1 million with approval of the lender for each advance.

The company estimates that the operative expenses for the next 12 months will be EUR 2,5-2,8 million. Additionally the financial expenses and loan repayments will reach EUR 0,7 million . Furthermore the company reserves EUR 0,5 million for the investments in product and process development and production . The amount of investments and expenses depend on the management decisions.

To secure the operations, the company is preparing a share issue and calling an extraordinary shareholders meeting to decide on the matter to conveine on March 17th 2022. The company believes to raise the sufficient funds with the share issue.

#### **Shares and shareholders**

The market value of BBS at the end of December 2021 was EUR 15,3 million. The closing valuation on December 31st was EUR 2,19 The highest price during the review period was EUR 4,72 and the lowest EUR 1,71.

On December 31st 2021, BBS had 3 926 registered shareholders (3391 in 2020). All the shares are of the same series. There were and 6 981 525 registered shares (2020: 6571 525) on December 31st 2021. The number of treasury shares was 243 636. Each share is entitled to one vote. The Company's Board of Directors and the Managing Director as persons and through entities under their control had a total of 577 812 (576 219) shares representing 8% of the total shares.

The information on insider trading is published on company's website.

170 000 options have been allocated to key personnel, each option entitles to subscribe for one share.

The largest shareholders on December 31st 2021 were:

Finha Capital (1 060 .938 s.) 15,2%

Reisjärvi municipality (700 721 s.) 10.0%

Pekka Jalovaara (550 700 s.), 7,9%

Irma Halonen (369 276 s.) 5,3%

Ahti Paananen (333 379 s.) 4,8%

Panvest Oy (305 177 s.) 4,4%

Jukka Halonen (175 913 s.),2,5%

Euroclear Bank Belgium (175 169 198 s) .2,5%

City of Oulu I Ky (130 081 s.). 1,9%

Veronika Halonen (129 337 s.),1,9%

The top ten shareholders represent 56% of the total shares and votes of the company.

#### The Consolidated Companies and Other Closely Related Parties

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 had no other business.

BBS had no shares in any other companies at the end of the review period.

The Board of Directors and the Managing Director are considered as the key personnel. The remuneration of the key personnel during the period was EUR 206 thousand (EUR 242 thousand in 2020)

The related parties of the Company include the members of the Board of Directors and their related parties, as well as the Company's management key personnel and their close associates. In the financial year 2020, there were no related party transactions.

#### **Events after the balance sheet date**

The company has raised the second tranche, EUR 250 thousand based on the Riverfort Global Opportunities Plc Financing Arrangement published on September 30th 2021. Following the transaction there is a remaining financial facility of EUR 1 Million available according to the agreement. Furthermore the company has signed a loan commitment agreement from Finha Capital oy for a facility of EUR 450 thousand, enabling raising the capital when needed. The final terms and conditions will be agreed in conjunction with the transaction.

#### Outlook for 2022

The company's goal is to submit the CE marking application to the authorities during the current spring.

Preparations for commercial operations will begin in autumn 2022.

The Board of Directors has prepared a detailed cash flow model that extends to 24 months from the financial statements. The model contains assumptions based on the Government's view of future developments, which are expected to prevail during the forecast period. Based on the model, the Board of Directors assesses the adequacy of the company's cash resources from the perspective of business continuity and the planning of measures.

Based of the information available together with the presented and initiated actions for raising finance, the company expects to secure the working capital over the next 12 months, mitigating the working capital risk.

However, despite all the actions presented, there remains a level of uncertainty in the sufficiency of the company finance .

# **Dividend proposal**

The Board of Directors of BBS proposes that no dividend shall be paid for the financial year 2021 and that the loss EUR -2770914,11 for the financial year is recognised in the profit/loss account.

#### **Accounting Policies**

The financial statements bulletin has been prepared in accordance with the Finnish Accounting Act and the rules of the First North Marketplace. The figures in the financial statements release are unaudited.

**Financial information 2022** 

BBS-Bioactive Bone Substitutes' Annual General Meeting 2022 is tentatively scheduled to be

held in Ouluon April 28th, 2022 at 2:00 PM. The Board of Directors will later send a separate

invitation to the meeting.

The Annual Report 2021 will be published on the Company's website in

week 13. Half-year report January-June 2022 made available by August

25th 2022.

Oulu, February 24th, 2022

**BBS-Bioactive Bone Substitutes Plc** 

Board

For more information:

Ilkka Kangasniemi, CEO,

puh. 040 7080307, e-mail: ilkka.kangasniemi@bbs-artebone.fi

This is information that BBS-Bioactive Bone Substitutes Plc is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the

agency of the contact person set out above on 24 February 2022 at 12:00 (UTC+2:00).

BBS – Bioactive Bone Substitutes Plc

BBS-Bioactive Bone Substitutes Plc is the health technology company operating since 2003. Before

that there was a background of seven years of product development in the University of Oulu. We

have developed a new product for healing of difficult bone fractures and for solving the problems in

bone healing. Our mission is to offer new generation medicinal products for the orthopedic surgery.

The research and development in the field of medicine requires perseverance and courage to

develop new things. We have over 20 years of expertise in this. Our operations are characterized by

top expertise, innovativeness and dedicated and committed employees. The ARTEBONE ®product

is ready and the application process for the CE marking has been initiated. BBS is the company

having its headquarters in Oulu. We have our own production plant located in Reisjärvi and it is

approved by FIMEA.

More information: www.bbs-artebone.fi.

BBS-Bioactive Bone Substitutes Plc shares are listed on the Nasdaq First North Growth Market

Finland and Nasdaq First North Growth Market Sweden. The company's Certified Adviser is

Nordic Certified Adviser AB, they can be reach on phone +46 70 551 67 29 or e-mail

info@certifiedadviser.se

**Distribution:** 

Nasdaq Helsinki Oy

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Main Media

www.bbs-artebone.fi

**ATTACHMENTS:** 

1. BBS Financial statement release for 2021

2. Financial Statement December 31, 2021 (Signed by the Company, unaudited)

3. Attachment to the Financial Statement Signature Kirk Andriano