

**BBS-Bioactive Bone Substitutes Plc's Half-Year report January 1<sup>st</sup> –June 30<sup>th</sup> 2021  
(Unaudited)**

**January-June 2021 shortly (comparison period 1-6/2020)**

**Events shortly**

- Company's operations have grown and significant investments into production have been made. As a result the cash expenditure has grown significantly.
- During the first half of the year and after that, delivery delays, non-conformities and equipment failures have occurred leading to delays regarding the CE marking process. Company's estimate of the delays for CE marking application filing is not accurate at the time of the release and it will be published as soon as possible but at latest at the end of September.
- The company had no net sales during the period under review
- Consolidated loss for the period was -1,31 (-1,42) M€.
- Operating cash flow for the first half of 2021 was -1,365 (-0,950) M€.
- Company cash reserves 30.6.2021 were 1,934 (5,019) M€.

**Key Figures**

€ 1000	1-6/2021	1-6/2020	1-12/2020
Other operating income	45	18	46
Personnel expenses	479	334	795
Depreciation and Amortisation	113	100	214
	663	960	1599
Profit /Loss for the period	-1 308	-1420	-2 731
The Cash Flow from Business Operations	-1 365	-950	-2 418
Equity ratio %	42,3	51,7	48,0
Earnings per share, EPS €	-0,20	-0,27	-0,46
Earnings per share €, diluted	-0,19	-0,26	-0,45
Number of shares at the end of period (BBS)	6 571 525	6 571 525	6 571 525
Average number of shares during the period	6 571 525	5 220 006	5 879 533

€ 1000	30.6.2021	30.6.2020	31.12.2020
Cash and cash equivalents	1 934	5 019	3 438
Capital and Reserves	4 780	7 399	6 078
Balance Sheet Total	11 303	14 301	12 693

\* *Equity Ratio*= 
$$\frac{\text{Equity}}{(\text{Balance Sheet Total} - \text{Advances Received})}$$

\* *EPS*= 
$$\frac{\text{Profit(Loss)}}{\text{Average number of Shares during the Period}}$$

**Guidance for 2021**

No net sales are expected for 2021, as due to delays, the CE mark will not be obtained during 2021.

## **Outlook for 2022**

Company will finalise the CE-marking process. Finalising production process transfer to commercial production readiness. Company is seeking additional funding to secure continuation of development and operations.

## **Ilkka Kangasniemi, CEO**

The first half of 2021 has been both challenging and positive regarding the goals of the company. Challenges imposed by Covid19 have mainly reflected in delays of equipment deliveries and shortage of supplies. The company's operations during the first half of 2021 have focused on finalizing the CE marking application. The operations have included, among others, animal study analysis and report finalization, scaling of production processes and transfer into commercial production, implementation of quality system and personnel education and training.

The main goal of the company, filing of the CE-marking application has already been delayed on several occasions for a variety of reasons. Regardless, we have been closing in on the filing steadily on many fronts. The company has initiated the transfer of the R&D phase production into commercial production in the beginning of the year, which is reflected in significant investments into equipment and personnel. The task has been significantly greater than originally believed. It must be remembered, that the product involves many more process steps than usually seen in the production of medical devices. Artebone® Paste consists of, in addition to a ceramic implant material component, a medicinal substance of animal origin. Thus, the production process involves a widest regulatory and quality requirement set possible for a medical device. Also, the number of production steps is unusually high. Thus, it is understandable how the R&D production phase transfer into commercial production is an unusually great effort and it includes a high number of individual processes that all must be verified and validated.

In the beginning of the year the company estimated that it would be able to submit the CE-marking application to authorities by April 2021. New issues emerged during the spring leading to postponement of the application filing to August. During summer equipment, material and service deliveries to Reisjärvi and Oulu locations were significantly delayed due to Covid19. In Reisjärvi clean room facility a structural fault was discovered in May, and the repair work delayed the onset of validation process. In addition, the animal study report delivery has been delayed significantly from what was prognosed earlier.

## **Essential events after the review period**

In June, the first extract production process was initiated as a part of the process validation. In July, after the process was finished a non-conformity was discovered in the process. Later, in August, it was discovered that also the quality tests did not meet the specifications. The problem was identified in the intermediate deviation in the bone processing process caused by the new equipment performance. In addition water purification equipment break down was discovered simultaneously. For these reasons the validation process had to be postponed earliest at October, therefore delaying also the CE-marking filing. Thus the company is not yet able to announce precise new CE marking application schedule, but will provide further information at latest by the end of September.

For the reasons mentioned above the company has had to use significantly more cash resources than prognosed in the beginning of the year. This has been necessary to keep up with the timelines as well as possible and to get the personnel and processes to comply with the requirements.

### **Board of Directors estimate of the upcoming development**

Submitting the CE marking application has been delayed and due to the long processing times of the Notified Body, the company will not receive the CE-marking during 2021.

To achieve positive development of the company, significant investments have been made into production and personnel. Due to additional expenditure created by these actions the company has initiated preparations in spring 2021 to acquire new equity. The Board estimates the current funding to last until the end of the year, in contradiction to earlier prognosis. The additional financing options under preparation include both debt and equity solutions. The Board will publish a new company release of how it intends to secure its short-term financing, at latest in the end of September. During the last quarter of this year the company initiates preparations for a potential share issue. The funds raised will ensure the continuity of the company's operations during the CE marking process and the start of sales.

### **FINANCIAL REVIEW January 1st –June 30th 2021 (Unaudited )**

#### **General**

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.

#### **Operating income and development costs**

BBS Plc had no revenue during the 1st half of financial year 2021, nor in the corresponding period of the previous year. The consolidated result for the review period was EUR -1,31 million (EUR -1,42 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 107 thousand ( EUR 25 thousand in 2020 ). All the development expenses were recognised as costs in the Profit and Loss statement.

The Company's cash resources at June 30th 2021 were EUR 1,93 million (EUR 5,02 million in 2020) and decreased during the review period of January 1st to June 30th by EUR 1,50 million. In 2020 the change in the cash position during the corresponding period was EUR 4,5 million.

The Company estimates that the current cash resources are sufficient for this year's expenses. The decisions of the Company's management can affect the cash flow.

The Company's cash flow from operating activities during the review period was EUR -1,37 (-0,95) million.

### **Acquisitions and Share Issues**

There were no mergers or acquisitions during the financial year.  
The total amount of the Company shares during the review period was 6 571 525.

### **Balance Sheet**

The balance sheet total at June 30th 2021 was EUR 11,30 million (EUR 14,30 million in 2020). At the end of the review period the short term debts amounted to EUR 1,43 million (EUR 0,95 million in 2020), out of which EUR 1,06 (0,31) million were interest bearing loans to credit institutions. The long-term interest-bearing debts amounted to EUR 4,74 ( 5,58) million and subordinated Capital Loan EUR 0,18 million (0,18). The financing costs were EUR -0,04 million (- 0,04 million in 2020)

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

### **Equity**

The Company's equity at June 30th 2021 was EUR 4,78 (7,39) million.  
At closing of the financial year December 31st .2020 the equity amounted to EUR 6,09 million.

### **Shares and shareholders**

The market value of BBS at the end of June 2021 was EUR 18,9 million. The closing valuation on June 30 th was EUR 2,89. The highest price during the review period was EUR 4,80 and the lowest EUR 2,49.

On June 30 th 2021, BBS had 3 671 registered shareholders. Respectively there were 2341 shareholders on June 30 th 2020 the number of shares being 6 571 525.

The Company's Board of Directors and the Managing Director as persons and through entities under their control had a total of 576 219 (576 219) shares representing 8,8% of the total shares. Information on the company's insider trading in the company's shares is published on the company's website.

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

The company has a valid 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. 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 three percent (3%) of the total, this has no perceptible impact on the earnings or other key figures per share.

### **Staff, management and administration**

At the end of the review period 2021 the company employed the Managing Director and 16 staff members (Total of 12 in 2020) . Two new personnel were recruited for the production. 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 Director Soile Hakala and Director of QC Mikko Viitanen. CFO Hannu Säynäjäkangas retired on February 1st 2021 and Ms Liisa Hukka was appointed as the new CFO and invited to the Management Team.

Ernst&Young Oy Authorised Public Accountants, was re-elected as the auditor of the Company by the AGM on April 28th having Mr Jari Karppinen (Auditor certified by the Central Chamber of Commerce) as the auditor with principal responsibility.

### **Valid Authorisations by AGM**

The Annual General Meeting on April 28th 2021 authorised the Board to decide on the issuance of a share issue that does not exclude the right of the Board to decide on a directed share issue. The share issue may be exercised to increase the share capital by issuing a share issue or convertible bonds in one or more instalments under the following rules: The Board is authorised to decide to increase the share capital by issuing a share issue, issuing a convertible loan, or issuing stock options in one or more instalments. In the new issue or alternatively, convertible loans or stock options may entitle to subscribe for a maximum of 3.000.000 (three million) new shares.

The authorisation includes the right to deviate from the shareholders' pre-emptive right to subscribe for new shares, convertible loans or warrants and to decide on the subscription prices, subscription rights and subscription terms. The subscription price of the shares is recorded in the invested unrestricted equity fund. The authorisation may be used in deviation from shareholder's pre-emptive subscription right, provided that there is a significant financial reason for the company, such as the extension of the company's shareholder base or another essential business interest or an arrangement to safeguard financial liquidity. Under the authorization, shares may be offered in deviation from shareholder's pre-emptive rights to the related party but not for the benefit of related parties. The Board is entitled to decide that shares can be subscribed for against payment of assets,

by using the right of set-off or otherwise on specific terms. Possible options are used at the discretion of the Board.

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

## **Risks and uncertainties**

The postponement in submitting the CE marking application and the growth in the expenditure has affected the sufficiency of the Company Funding. Based on Managements' judgement, no other significant changes in risks and uncertainties have been recorded during the first half of FY2021.

As informed in the Financial Review for FY2020, 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 expected to be available shortly.

The FDA registration process has been started. The matters causing delays in the CE application process may also reflect the FDA registration. In the US, there is a fundamental risk in the 510 (k) approval route that allows the use of precedents. But according to the company's current knowledge, no difficulties are expected in these areas.

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 still 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.

## **Events after the review period**

After the review period a non-conformity was discovered in the extract production process together with an equipment breakdown, thus postponing the validation processes. This in turn has affected the timetable of submitting the CE Marking application, postponing it further.

## **Half-year reporting principles**

The half-yearly 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.

## **Financial information 2022**

The Financial Statements Review for the whole financial year 2021 will be published on March 23rd 2022.

The Interim Report H1/2022 will be released in August 31st, 2022.

## **ATTACHMENTS**

The Profit and Loss Account and The Balance Sheet on June 30th 2021

The Cash Flow Statement on June 30th 2021

The Statement of Changes in Equity as June 30th 2021

Income statement (unaudited)	01/01/2021	1.1.2020	1.1.2020
Currency unit EURO	- 30.6.2021	- 30.6.2020	- 31.12.2020
<b>NET TURNOVER</b>	0,00	0,00	0,00
Other operating income	44 974,42	18 409,69	45 634,39
Raw materials and services			
Raw materials and consumables			
Purchases during the financial year	-56 949,57	0,00	-83 061,22
External services *	0,00	0,00	0,00
Raw materials and services total	-56 949,57	0,00	-83 061,22
Personnel expenses			
Wages, salaries and bonuses	-403 975,66	-291 255,92	-675 231,30
Social security expenses			
Pension expenses	-69 280,59	-38 131,40	-90 529,05
Other personnel expenses	-6 181,83	-4 930,02	-29 058,87
Personnel expenses total	-479 438,08	-334 317,34	-794 819,22
Depreciation, amortisation and impairment losses			
Planned depreciation and amortisation	-112 530,63	-99 847,65	-213 994,51
Planned depreciation and amortisation total	-112 530,63	-99 847,65	-213 994,51
Other operating charges	-662 546,55	-960 016,81	-1 598 825,86
<b>OPERATING PROFIT (LOSS)</b>	<b>-1 266 490,41</b>	<b>-1 375 772,11</b>	<b>-2 645 066,42</b>
Financial income and expenses			
Other interest and financial income			
From others	23,92	1,12	2,27
Interest and other financial expenses			
For others	-41 059,90	-43 938,32	-85 916,65
Financial income and expenses total	-41 035,98	-43 937,20	-85 914,38
<b>PROFIT (LOSS) BEFORE EXTRAORDINARY ITEMS</b>	<b>-1 307 526,39</b>	<b>-1 419 709,31</b>	<b>-2 730 980,80</b>
<b>PROFIT (LOSS) FOR THE FINANCIAL YEAR</b>	<b>-1 307 526,39</b>	<b>-1 419 709,31</b>	<b>-2 730 980,80</b>

## Balance Sheet (unaudited)

Currency unit EURO	30/06/2021	30/06/2020	31.12.2020
<b>ASSETS</b>			
<b>NON-CURRENT ASSETS</b>			
Intangible assets			
Development expenses	7 532 827,55	7 532 827,55	7 532 827,55
Other capitalised long-term expenses	282 271,58	333 593,66	307 932,62
Intangible assets total	7 815 099,13	7 866 421,21	7 840 760,17
Tangible assets			
Land and waters			
Own	83 719,00	83 719,00	83 719,00
Buildings			
Own	462 652,75	497 476,07	479 432,89
Machinery and equipment	677 345,25	653 431,00	640 185,50
Tangible assets total	1 223 717,00	1 234 626,07	1 203 337,39
<b>NON-CURRENT ASSETS TOTAL</b>	<b>9 038 816,13</b>	<b>9 101 047,28</b>	<b>9 044 097,56</b>
<b>CURRENT ASSETS</b>			
Debtors			
Short-term			
Other debtors	330 333,74	180 965,20	210 433,63
Prepayments and accrued income	53,33	0,00	53,33
Debtors total	330 387,07	180 965,20	210 486,96
Cash and cash equivalents	1 934 269,74	5 019 391,16	3 438 153,89
<b>CURRENT ASSETS TOTAL</b>	<b>2 264 656,81</b>	<b>5 200 356,36</b>	<b>3 648 640,85</b>
<b>ASSETS TOTAL</b>	<b>11 303 472,94</b>	<b>14 301 403,64</b>	<b>12 692 738,41</b>

## Balance Sheet (unaudited)

### LIABILITIES

	30/06/2021	30/06/2020	31.12.2020
<b>CAPITAL AND RESERVES</b>			
Share capital			
Share capital	80 000,00	80 000,00	80 000,00
	80 000,00	80 000,00	80 000,00
Share premium account	1 394 956,56	1 394 956,56	1 394 956,56
Other funds			
Invested unrestricted equity fund	17 377 537,93	17 377 537,93	17 377 537,93
Other funds total	17 377 537,93	17 377 537,93	17 377 537,93
		-10 034	
Retained earnings (loss)	-12 765 193,41	212,61	-10 034 212,61
Profit (loss) for the financial year	-1 307 526,39	-1 419 709,31	-2 730 980,80
<b>CAPITAL AND RESERVES TOTAL</b>	<b>4 779 774,69</b>	<b>7 398 572,57</b>	<b>6 087 301,08</b>
<b>CREDITORS</b>			
Long-term			
Capital loans	175 825,46	175 825,46	175 825,46
Loans from financial institutions	4 740 583,00	5 585 314,00	5 529 499,00
Accruals and deferred income	176 200,00	176 200,00	176 200,00
Long-term loans total	5 092 608,46	5 937 339,46	5 881 524,46
Short-term			
Loans from financial institutions	1 063 544,00	306 728,00	306 728,00
Trade creditors	120 285,62	99 483,19	145 118,76
Other creditors	46 273,43	365 702,92	40 719,43
Accruals and deferred income	200 986,74	193 577,50	231 346,68
Short-term total	1 431 089,79	965 491,61	723 912,87
<b>CREDITORS TOTAL</b>	<b>6 523 698,25</b>	<b>6 902 831,07</b>	<b>6 605 437,33</b>
<b>LIABILITIES TOTAL</b>	<b>11 303 472,94</b>	<b>14 301 403,64</b>	<b>12 692 738,41</b>

## Cash flow statement (unaudited)

[1000 euros]	1.1-30.6.2021	1.1-30.6.2020	1.1.-31.12.2020
<b>Cash flow from business operations</b>			
<i>Profit (loss) before extraordinary items</i>	-1308	-1420	-2731
Adjustments			
Scheduled depreciation and amortisation	113	100	214
Financial income and expenses	41	44	86
Other adjustments			
<b>Cash flow before changes in working capital</b>	<b>-1154</b>	<b>-1276</b>	<b>-2431</b>
Change in working capital			
Changes in short-term non-interest-bearing (+) (-)	-120	-40	-70
Changes in inventory Increase (-)/ Decrease (+)	0	0	0
Changes in short-term non-interest-bearing loans Increase (+)/Decrease (-)	-30	259	-7
Changes in long-term non-interest-bearing loans Increase (+)/Decrease (-)	0	176	176
<b>Cash flow from business operations before financial items and taxes</b>	<b>-1304</b>	<b>-881</b>	<b>-2331</b>
Interest paid and other financial expenses from business operations	-61	-69	-87
Interest received and other financial income from business operations	0	0	0
Cash flow before extraordinary items and taxes	-1365	-950	-2418
<b>Cash flow from business operations (A)</b>	<b>-1365</b>	<b>-950</b>	<b>-2418</b>
<b>Cash flow from investments</b>			
Investments in tangible and intangible goods	-107	-25	-82
Investments in shares in subsidiaries	0	0	0
Loans granted			
<b>Cash flow from investments (B)</b>	<b>-107</b>	<b>-25</b>	<b>-82</b>
<b>Cash flow from financing</b>			
Share issue	0	5739	5739
Raised long-term loans	0	0	0
Repayment of long-term loans	-32	-261	-317
Raised short-term loans	0	0	0
Repayment of short-term loans	0	0	0
<b>Cash flow from financing (C)</b>	<b>-32</b>	<b>5478</b>	<b>5423</b>
<b>Changes in funds (A+B+C) Increase (+)/Decrease (-)</b>	<b>-1504</b>	<b>4504</b>	<b>2923</b>
Funds at the beginning of the financial period	3438	516	516
Funds at the end of the financial period	1934	5019	3438

## Specification of equity

1000 euro	Share capital	Share premium account	Invested unrestricted equity fund	Accumulated profits	Equity, total
<b>Equity, total 1.1.2021</b>	<b>80</b>	<b>1395</b>	<b>17377</b>	<b>-12765</b>	<b>6087</b>
Profit/loss for the financial year				-1307	
Paid share issue					
<b>Equity, total 30.6.2021</b>	<b>80</b>	<b>1395</b>	<b>17377</b>	<b>-14072</b>	<b>4780</b>
<b>Equity, total 1.1.2020</b>	<b>80</b>	<b>1395</b>	<b>11638</b>	<b>-10034</b>	<b>3079</b>
Profit/loss for the financial year				-1419	
Paid share issue			5739		
<b>Equity, total 30.6.2020</b>	<b>80</b>	<b>1395</b>	<b>17377</b>	<b>-11453</b>	<b>7399</b>
<b>Equity, total 1.1.2020</b>	<b>80</b>	<b>1395</b>	<b>11638</b>	<b>-10034</b>	<b>3079</b>
Profit/loss for the financial year				-2731	
Paid share issue			5739		
<b>Equity, total 31.12.2020</b>	<b>80</b>	<b>1395</b>	<b>17377</b>	<b>-12765</b>	<b>6087</b>

*During the comparison period January 1<sup>st</sup> – June 30<sup>th</sup> 2020 the development costs (63339,24€) originally presented as outsourced services have been transferred to other operating cost for comparison purposes.*