

BBS-Bioactive Bone Substitutes Oyj  
Interim information

## **Correction to the regulatory release of BBS-Bioactive Bone Substitutes Plc published on 31.8.2020 at 12:15 CET**

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The release of interim report published by BBS-Bioactive Bone Substitutes Plc on 31.8.2020 at 12:15 CET has been supplemented. A clause in accordance with the Market Abuse Regulation, contact information and a brief description of the company have been added to the release. In additionally, Finnish and English versions have been unified. The corrected release is in entirety below.

### **BBS-Bioactive Bone Substitutes Plc (BBS) Interim Report 1.1.-30.6.2020 (unaudited)**

#### **January-June shortly (comparison season 1-6/2019)**

- The Company published the results of its first clinical investigation in February 2020. The study was performed in connection with fusions of ankle and subtalar joints. According to the results, ARTEBONE® product tested to be safe and functional can replace similar autograft treatment in the future.
- The company will continue to update its quality system in accordance with the requirements of new Medical Device Regulation (MDR 2017/745). The date of entry into force of the changes to the regulation has been postponed one year until 5/2021 by the decision of European Commission.
- The contract of handling of the company's first product CE marking application was requested from Notified Body (BSI) in good time in December 2019. The goal was to get it processed in March 2020. However, BSI replied that it will not be able to process new applications until June due to pressures of the changes of MDR. The company did not receive the draft of contract until in July in this year.
- The preliminary results of animal study commissioned by the company have been received in June and July. A review of the results revealed that they support the objectives that the company has set for the study. The final report will be expected in September according to the original plan.
- The right issue and the directed issue raised a total of approximately EUR 574 million new gross capital, of which approximately EUR 505 million remained after the expenses related to the share issues. A short-term loan of EUR 200.000 was converted into issues, so the net cash flow was EUR 4,85 million.
- The company's investment and working capital loans have been restructured
- Ernst & Young Oy was elected as a company's auditor, KHT Jari Karppinen as the principal auditor and KHT Milla Karjalainen as the deputy auditor
- The company had no net sales during the period under review
- The cash flow from operations was EUR 0,750 (0,786) million
- BBS's cash assets on 30<sup>th</sup> June 2020 was EUR 5,019 (0,878) million

## Key financial figures

1000 euros	1- 6/2020	1- 6/2019	1- 12/2019
Other operating income	18	29	2 262
Personnel expenses	334	350	670
Depreciation and impairments	100	112	229
Other operating expenses	897	340	757
Operating profit (Loss) of the period	-1 376	-809	-447
Cash flow from business operations	-950	-786	-1 701
Equity ratio %	50.3	34,6	39,6
Earnings per share €	-0,27	-0,16	-0,076
The number of the shares at the end of the period	6 571 525	5 090 520	5 204 820
The average number of the shares during the period	5 220 006	5 090 520	5 148 453

1000 euros	30.6.2020	30.6.2019	31.12.2019
Cash and securities	5 019	878	1 685
Equity	7 399	3 558	4 417
Equity and liability total	14 301	10 298	11 156

The equity ratio = equity/equity and liabilities total

Earnings per share = earnings for the period/the average number of the shares during the period

### Guidance for 2020

For the year 2020, substantial net sales are not expected to be generated. CE marking will not to be obtained during 2020.

### Outlook for 2021

The company will complete the processing of the CEmarking application with the Notified Body at the beginning of the year. The company's production processes are being prepared to start the actual production. Preparations for the marketing and sales have already begun in 2020, and preparations for the launch will continue from the beginning of the year. The launch expected to begin between April and June 2021. From the end of the year 2021, the development of turnover is expected to start even more slowly, as is typical for the industry.

### Ilkka Kangasniemi, CEO

The first half of 2020 was significantly more positive for the company than the previous year. The positive result of the clinical trial published by the company in the early part of the year contributed to the successful share issue in June 2020. As a result of the issues, the company

raised a total of EUR 5,74 million gross in in Finnish and Swedish First North Growth Market lists. The issue was marked about one and half times over. We are pleased to say that the company has been able to operate for about two years at turning point in the company's future. We expect the company to receive a marketing authorization for its first ARTEBONE® product during spring 2021.

In spring 2020 we still had to experience the effects of the problem that arose on the part of the authorities in our operations. Due to new medical Device Regulation (MDR 2017/745), the Notified Body (BSI) with which we have previously worked and from which we requested a new contract for the processing of the application was unable to receive the application here for half a year, because the regulation caused a large change of appeal is if congested by their organization. By EU-commission decision, the date of entry into force of the amendments to the regulation has been postponed May 2021. Then the congested work queue of the Notified Body was released and in June 2020 we received a contract from BSI for approval. So, we finally got the CEmarking process to start one.

Preliminary results from an animal test carried out at the request of authority was obtained in June 2020. The results were as expected. The timetable for obtaining the final results is expected to be confirmed by the supplier.

Marketing and sales construction activities will begin when the authority receives the first positive interim information on the questions and comments raised by the processing of the application. We will then implement in the end of 2020 sales recruitment and measures. Due to the long-term nature of marketing, it is necessary to start these measures months before the actual launch.

## **FINANCIAL REVIEW 1st January – 30th June, 2020**

### **Overall**

BBS owns 100% of the subsidiary Bio Bones Oy, which owns the real estate for production in Reisjärvi. Bio Bones has no other business.

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

BBS did not have any significant net sales during the review period and the corresponding period of the previous year.

### **Financing and investments**

The company's cash assets at 30<sup>th</sup> June 2020 were EUR 5,019 (0,878) million. The company estimates that the current funding will be adequate approximately two year after the date of this release. The company's management may decide on the adequacy of money.

The group's cash flow from operating activities during the review period was EUR -0,950 (-0,786)

## **Acquisitions and directed share issues**

No acquisitions were made during the review period.

In June 2020, a rights issue was arranged in Finland and Sweden. The offer comprised up to 1.301.205 new shares, representing approximately 25% of the company's existing shares, for subscription by investors. 1.059.634 shares were subscribed for the rights issue and the remaining 241.571 shares were issued for allocation in accordance with the terms of the share issue. The company organized a rights issue in June 2.-18.2020. The rights issue raised EUR 5,47 million worth in gross assets. Following the rights issue, it became apparent that the subscription and payment of 65.500 shares of an existing shareholder who had given a commitment, has not been registered by the Board of Directors on 24<sup>th</sup> June 2020 allocation. On June 26, 2020, the Board of Directors decided to direct the issue of 65.500 share to this investor at the same subscription price as in the subscription's rights issue was. EUR 0,27 million was collected by the directed share issue. EUR 5,74 million gross was received from issues. A short-term loan of EUR 0,200 million was converted into shares in connection with the right issue. After the shares issue fees, loan conversion and the share issue cost, approximately EUR 4,85 million remained in cash.

After the subscription on June 29, 2020, of the rights issue and directed issue, the total number of the company's share is 6.571.525.

## **Balance sheet**

The consolidated balance sheet total on 30<sup>th</sup> June 2020 was EUR 14,30 (10,30) million. On the 30<sup>th</sup> June 2020 the company had a short-term debts EUR 1,34 (1,37) million, long-term loans to financial institutions EUR 5,76 (5,37) million, capital loans of EUR 0,18 (0,18) million. Financial income and expenses amounted to EUR -0,04 (-0,05) million.

The company's investment and working capital loans amounts of EUR 78.520, EUR 1.844.212, EUR 2.732.000, ja EUR 578.680 was restructured in March 2020. Repayments of restructured loans will begin on June 30, 2020 and end on June 30, 2028. The arrangement will significantly reduce the debt service burden.

During the review period no capitalized and product investments have been made in balance sheet.

## **Equity**

Equity on 30th June 2020 was EUR 7,20 (3,56) million. In the financial statement at December 2019, the shareholders equity was EUR 3,08 million.

## **Staff and administration**

The number of employees was 12 at the end of review period on 30<sup>th</sup> June 2020. Members of the board were Jarmo Halonen (chairman), Ilkka Kangasniemi, Auvo Kaikkonen, Tomi Numminen, Pekka Jalovaara and Hannu Säynäjäkangas. Ilkka Kangasniemi is acting as the CEO.

## **The annual general meeting 2020**

The annual general meeting (AGM) of BBS was held in Oulu on 17<sup>th</sup> August 2020.

The AGM approved the financial statements for 2019 and discharged the members of the board of directors and the CEO from liability. The AGM decided, in accordance with the proposal of the board of directors, that no dividend be paid for the financial year 2019 and that the loss for the financial year is recorded in the profit/loss account.

The AGM approved the remuneration of board members for EUR 500 and for the chairman EUR 750 per meeting.

The AGM decided that a reasonable fee would be paid to the auditor in accordance with the invoice approved by the company. Auditing society Ernst&Young Oy was elected as the auditor of BBS, with KHT Juhani Rönkkö as the principal auditor and KHT Milla Karjalainen as a deputy auditor.

## **Share-based incentive plan**

The company has a valid stock option program for 2012 approved by the AGM in 18th July 2012. The board of directors has decided on options for the 2th January 2013 as authorized by the AGM. Options have been issued to key personnel and by each option can subscribe for one share at the price of one euro until 31th December 2019. The board of directors, on 9<sup>th</sup> January 2018, continued the subscribe period until 31th December 2023. Stock options may be issued up to 170 000 new shares and this has no perceptible impact on the earnings per share.

## **Risks and uncertainties**

The rights issue and directed issue carried out during the review period have significantly reduced the financing risk in the near future. Investment and working capital loans restructuring in March 2020 have also lowered the financial risk. The CE marking process schedule has been refined. In the opinion of the management, there have been no significant changes in the risks and uncertainties related to the company's business in the first half of 2020.

There are significant risks and uncertainties associated with product development and commercialization that are beyond the control of the company, such as regulatory actions, regulatory changes and market willingness to receive a new product. Capitalization and capitalization of confirmed losses is not certain.

## **Shares and shareholders**

The BBS's market capitalization at the end of the review period of outside the company 30<sup>th</sup> June 2020 was EUR 30,2 million. The closing price of the share on 30th June 2020 was EUR 4,60. The highest price for the review period was EUR 9,68 and the lowest was EUR 4,00.

BBS had 2341 (1025, 28<sup>th</sup> June 2019) registered shareholders and 6 572 525 (5 090 520), according to a register of shareholders dated 30<sup>th</sup> June 2020.

The BBS's board of directors and the CEO held 30<sup>th</sup> June 2020 total of 576 219 (543 650) shares including shares held through controlled companies, i.e. 8,8% of the company's shares. Information about the company's insider trading in the company's shares is published on the company's website.

### **Event after the review period**

In order to enable the participants in the right issue to participate equally in the Annual General Meeting, scheduled for June 28, 2020, the AGM was postponed to August 17, 2020. The decisions of the AGM have been announced separately after the review period.

After the review period, a contract was received from Notified Body in July 2020 to start the process of CEmarking of the ARTEBONE® product. BBS accepted the agreement and has begun preparations with BSI to launch the process.

### **Half-year accounting principles**

The half-yearly review has been prepared in accordance with the Finnish Accounting Act and rules of the First North marketplace. Figures for the half-yearly review are unaudited.

### **Financial information 2021**

The financial statement bulletin for January-December 2020 will be published on 20<sup>th</sup> March 2021. Interim Report H1/2021 will be released in August 31<sup>st</sup>, 2021.

### **ATTACHMENTS:**

Financial Statement 30th June 2020  
Cash Flow Statement 30<sup>th</sup> June 2020  
Statement of changes in equity

### **Distribution:**

Nasdaq Helsinki Oy  
Nasdaq Stockholm AB  
Main Media  
[www.bbs-artebone.fi](http://www.bbs-artebone.fi)

### **For more information:**

BBS-Bioactive Bone Substitutes Plc  
CEO Ilkka Kangasniemi  
Phone: +358 40 7080307  
E-mail: [ilkka.kangasniemi@bbs-artebone.fi](mailto: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 31 August 2020 at 16:10 am (UTC +3.00).*

## About BBS

BBS-Bioactive Bone Substitutes Plc is a Finnish orthobiologic biotech company. 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 first product, ARTEBONE® paste, is ready and the application process for the CE-marking enabling commercialization is in progress.

More information: [www.bbs-artebone.fi](http://www.bbs-artebone.fi).

The company's Certified Adviser Stockholm Certified Advisers AB, p. +46 70 5516 729, [info@certifiedadviser.se](mailto:info@certifiedadviser.se)

	1.1.-30.6. 2020	1.1.-30.6. 2019	1.1.-31.1 2019
BBS-Bioactive Bone Substitutes			

## CONSOLIDATED INCOME STATEMENT

TURNOVER	0,00	0,00	
Other operating income	18 409,69	29 050,60	52 7
Material and services			
Raw material and consumables			
Purchase during the period	0,00	-6 996,90	-11 0
External services	-63 339,24	-29 399,36	-94 6
Raw materials and services total	-63 339,24	-36 396,26	-105 6
Personnel expenses			
Wages and salaries	-291 255,92	-301 676,59	-568 8
Social security expenses			
Pension expenses	-38 131,40	-41 883,80	-83 0
Other personnel expenses	-4 930,02	-6 159,02	-13 1
Personnel expenses total	-334 317,34	-349 719,41	-665 0
Depreciation and amortization			
Depreciation according to plan	-99 847,65	-112 388,67	-225 4
Impairment of non-current assets	0,00	0,00	
Depreciation and amortization total	-99 847,65	-112 388,67	-225 4
Other operating expenses	-896 677,57	-339 542,53	-592 5
OPERATING PROFIT (LOSS)	-1 375 772,11	-808 996,27	-1 535 9
Financial income and expenses			
Other interest income and other financing income			
From others	1,12	0,18	



## EQUITY

Share capital	80 000,00	80 000,00	80 000,00
Share capital total	80 000,00	80 000,00	80 000,00
Share premium account	1 394 957,01	1 394 957,01	1 394 957,01
Other reserves			
Invested unrestricted equity fund	17 377 537,93	11 337 847,26	11 638 453,75
Other reserves total	17 377 537,93	11 337 847,26	11 638 453,75
Retained earnings (loss)	-10 034 213,06	-8 396 062,95	-8 396 062,95
Profit (loss) of the period	-1 419 709,31	-859 046,12	-1 638 150,11
<b>CAPITAL AND RESERVES TOTAL</b>	<b>7 398 572,57</b>	<b>3 557 695,20</b>	<b>3 079 197,70</b>

## CREDITORS

Long term			
Capital Loans	175 825,46	175 825,46	175 825,46
Loans from credit institutions	5 585 314,00	5 191 297,00	5 191 297,00
Long term loans total	5 761 139,46	5 367 122,46	5 367 122,46
Short term			
Loans from credit institutions	306 728,00	963 793,00	961 473,00
Trade creditors	99 483,19	23 123,41	31 879,90
Accrual income	365 702,92	11 959,16	27 293,22
Referred income	369 777,50	374 052,24	365 846,82
Short term creditors total	1 141 691,61	1 372 927,81	1 386 492,94
<b>CREDITORS TOTAL</b>	<b>6 902 831,07</b>	<b>6 740 050,27</b>	<b>6 753 615,40</b>
<b>EQUITY AND LIABILITIES TOTAL</b>	<b>14 301 403,64</b>	<b>10 297 745,47</b>	<b>9 832 813,10</b>

## CASH FLOW STATEMENT

	[thousand euro]	1-6/2020	1-6/2019	2019
<b>Cash flow from business operations</b>				
Profit (loss) before extraordinary items		-1420,00	-859	-1638
<b>Adjustments</b>				
Scheduled depreciation and amortization		100	112	225
Financial income and expenses		44	50	102
Other adjustments:		0	0	0
Other adjustments: Write-downs		0	0	0
<b>Cash flow before changes in working capital</b>		<b>-1276</b>	<b>-697</b>	<b>-1311</b>

<b>Change in working capital</b>			
Changes in short-term non-interest-bearing receivables Increase(-)/Decrease(+)	-40	-40	-47
Changes in inventory Increase(-)/Decrease(+)	0	0	0
Changes in short-term non-interest-bearing loans Increase(+)/Decrease(-)	435	25	18
<b>Cash flow from business operations before financial items and taxes</b>			
	<b>-881</b>	<b>-712</b>	<b>-1340</b>
Interest paid and other financial expenses from business operations	69	74	104
Interest received and other financial income from business operations	0	0	0
<b>Cash flow before extraordinary items</b>	<b>-950</b>	<b>-786</b>	<b>-1444</b>
<b>Cash flow from business operations (A)</b>	<b>-950</b>	<b>-786</b>	<b>-1444</b>
<b>Cash flow from investments</b>			
Investments in tangible and intangible goods	-25	-21	-24
Investments in shares in subsidiaries	0	0	0
Loans granted	0	0	0
<b>Cash flow from investments (B)</b>	<b>-25</b>	<b>-21</b>	<b>-24</b>
<b>Cash flow from financing</b>			
Rights issue	5739	0	301
Raised long-term loans	0	0	0
Repayment of long-term loans	261	0	2
Repayment of long-term loans	0	0	0
Repayment of short-term loans	0	0	0
<b>Cash flow from financing (C)</b>	<b>5478</b>	<b>0</b>	<b>299</b>
<b>Changes in funds (A+B+C) Increase (+)/Decrease (-)</b>	<b>4503</b>	<b>-807</b>	<b>-1169</b>
Funds at the beginning of the financial period	516	1685	1685
Funds at the end of the financial period	5019	878	516

### Equity development

	Share capital	Share premium account	Invested unrestricted equity fund	Accu-mulated profits	Equity	Total
Equity 31.12.2019	80	1395	11638	-10034		3079
Profit/loss in period				-1419		
Paid share issue			5739			
Equity 30.6.2020	80	1395	17377	-11453		7399
Equity 31.12.2018	80	1 395	11 338	-8 396		4 417
Profit/loss in period				-859		
Paid share issue						
Equity 30.6.2019	80	1 395	11 338	-9 255		3 558
Equity 31.12.2018	80	1 395	11 338	-8 396		4 417
Profit/loss				-1 638		
Paid share issue			300			
Equity 31.12.2019	80	1 395	11 638	-10 034		3 079