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BBS-Bioactive Bone Substitutes Oyj
Interim information

BBS Interim Report H1/2019

BBS-Bioactive Bone Substitutes Plc (BBS) Interim Report January 1th – June 30th 2019 (unaudited)

January-June shortly (comparison season 1-6/2018)

- Updates as required by the new Medical Device Regulation (MDR 2017/745) must be implemented by May 2020
- Validation of the production steps of the ARTEBONE® -final product is almost done, the final step of the validation of sterilization is under way
- For the final product has its own customized dosing syringe completed and validated
- Syringe filling equipment has been completed and validated for production
- An additional large animal test proposed by the authorities is under way
- The directed issue in Sweden resulted 215 new shareholders and about EUR 300.000 capital was received
- The company's investment and working capital loans have been restructured
- Ernst & Young Oy was elected as a company's auditor and KHT Jari Karppinen as the principal auditor
- The company had no net sales during the period under review
- The cash flow from operations was EUR 0,786 (1,153) million
- BBS's cash assets on 30th June 2019 was EUR 0,878 (2,270) million

Key financial figures

(1000) EUR	1-6/2019	1-6/2018	1-12/2018
Other operating income	29	*2 237	*2 262
Personnel expenses	350	356	670
Depreciation and impairments	112	112	229
Other operating expenses	340	588	757
Profit (Loss) of the period	-809	-1 076	-447
Cash flow from business operations	-786	-1 153	-1 701
Equity ratio %	34,6	42,8	39,6
Earnings per share €	-0,16	-21	-0,076
The number of the shares at the end of the period	5 090 520	5 090 520	5 090 520
The average number of the shares during the period	5 090 520	4 904 136	4 998 094

*Includes EUR 2,22 million of the accord accorded to loans during 2018

(1000) EUR	06/30/2019	06/30/2018	12/31/2018
Cash and securities	878	2 270	1 685
Equity	3 558	5 061	4 417
Equity and liability total	10 298	11 816	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 2019

For the year 2019, substantial net sales are not expected to be generated. CE marking will not to be obtained during 2019.

Outlook for 2020
BBS will perform additional animal studies and drive forward the CE marking process of the first product and launch sales and marketing preparations.

Pekka Jalovaara, CEO

BBS-Bioactive Bone Substitutes Plc (BBS) is a growing Finnish company that has developed a new bone implant, medical device, for treating of bone traumas, bone losses and bone defects. The company has the headquarters and quality control laboratory in Oulu and the EU-certified production facility at Reisjärvi. The company has a history of over 15 years, during which time the company has developed product and production methods, performed required preclinical and clinical tests, and established a manufacturing line and a quality system for commercial production. The product development phase of a company like BBS is typically 10-15 years and BBS has not been able to fall below this, especially when this is a brand-new product at the interface between a medical device and a medicinal product.

Our company still has no turnover, but the CE marking and FDA approval processes required for the product's marketing authorization are currently under way. Sales are expected to begin no later than next year as soon as the CE marking is received. Until now, BBS has been a product development company but is now heading for marketing and sales. Sales are expected to start in the Nordic countries and a few Central European countries, while investing heavily in partners.

ARTEBONE® product contains natural bone hard component, tricalcium phosphate mineral granules, as well as proteins including the bone growth factors that are extracted from reindeer bone. The product resorbs from the trauma when it heals. Currently there are products with only one of these components, but BBS has managed to combine these two. Our first product is a ready-to-use paste in the syringe so there is no need to make any mixing on the operating table, which is typical for competing products. ARTEBONE® product is based on its ingredients comparable to bank bone or human DBM (Demineralized Bone Matrix) products. DBM products have been found to poorly induce the formation of new bone. In addition, the quality of human-derived products may vary greatly depending on the age and health of the donor. The reindeer bone protein extract in ARTEBONE® is very homogeneous because bones from about 70 reindeer are used on one batch. Reindeer bone protein extract has been found safe in preclinical trials and no human viral diseases can be transmitted to patients. In clinical trial, ARTEBONE® has proven to be safe and functional.

Based on the studies carried out, the ARTEBONE® product can in future replace the most common currently used own bone grafts in the treatment of bone problems. This brings significant saving to the society, hospitals and patients. Own bone graft needs to be taken from your own body, typically from the iliac crest and this means additional surgery that takes time up to an hour. Surgical harvesting of bone also involves the risk of complications. With ARTEBONE® only one surgery is needed instead of two. Therefore, the hospitalization time is shortened, and the patient recovers more quickly.

Furthermore, our product is ecological because we use renewable materials in our premium products to promote people's health.

Our first short-term goal is to get marketing approvals and to open sales in the Nordic countries and

Europe. One of our main goals is to find a big partner to ensure global access to the market. Large companies in the industry do not do their own product development; instead they observe the small product development companies.

FINANCIAL REVIEW 1th January – 30th June, 2018

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. In other income the Tekes decision not to collect old product development loans of EUR 2,22 million has been recorded.

Financing and investments

The company's cash assets at 30th June 2019 were EUR 0,88 (2,27) million. The company estimates that the current funding will be sufficient through austerity measures approximately one year after the date of this release.

The groups cash flow from operations was EUR -0,79 (-1,15) million in the review period.

Acquisitions and directed share issues

No acquisitions were made during the review period.

In June 2019 a directed share issue was held in Sweden. The offer dealt maximum of 509 000 new shares, circa 10% of present number of shares in the Company, for subscription by investors on the swedish market. The company organized a directed share issue in Sweden on 17th – 30th June 2019. The reason for the deviation from shareholder's preference was to expand the company's shareholder base in Sweden and to increase trading volume. The result was not yet clear during the review period.

Balance sheet

The consolidated balance sheet total on 30th June 2019 was EUR 10,30 (11,82) million. On the 30th June 2019 the company had a short-term debts EUR 1,37 (0,53) million, long-term loans to financial institutions EUR 5,37 (6,22) million, capital loans of EUR 0,18 (0,18) million. Financial income and expenses amounted to EUR -0,05 (-0,05) million.

The company's investment and working capital loans amounts of EUR 641 668 and EUR 277 690 were renegotiated in June 2019. The loans would have fallen due in 2019 and 2020. Repayments on renewed loans begin at December 31th 2019 and end at December 31th 2024. The loan period is 5 year in equal installments every 6 months. 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 2019 was EUR 3,56 (5,06) million. In the financial statement at December 2018, the shareholders equity was EUR 4,42 million.

Staff and administration

The number of employees was 12 at the end of review period on 30th June 2019. Members of the board were Jarmo Halonen (chairman), Ilkka Kangasniemi, Auvo Kaikkonen, Tomi Numminen, Pekka Jalovaara and Hannu Säynäjäkangas. Pekka Jalovaara is acting as the CEO.

The annual general meeting 2019

The annual general meeting (AGM) of BBS was held in Oulu on 5th April 2019.

The AGM approved the financial statements for 2018 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 2018 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.

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 9th 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

Debt accord 2018 and investment and working capital loans restructuring in June 2019 and directes share issue in Sweden have lowered the near future financial risk. The European Commission's manual on medical devices reduced the risk associated with the classification of ARTEBONE®. According to the company's management, there are no significant changes in the risks and uncertainties associated with the business of BBS during the first half of 2019.

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. Adequacy of funding is associated with

uncertainties that may delay obtaining a marketing authorization.

Shares and shareholders

The BBS's market capitalization at the end of the review period of outside the company 30th June 2019 was EUR 15,8 million. The closing price of the share on 30th June 2019 was EUR 3,10. The highest price for the review period was EUR 3,75 and the lowest was EUR 2,06.

BBS had 1025 registered shareholders and 5 090 520, according to a register of shareholders dated 30th June 2019.

The BBS's board of directors and the CEO held 30th June 2019 total of 543 650 (543 650) shares including shares held through controlled companies, i.e. 10,7% 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

Ernst & Young has acted as the company's auditor and KHT Juhani Rönkkö as the principal auditor, who will be employed by another company. The new auditor elected by the Board of Directors from 1th September 2019 is Ernst & Young Oy and KHT Jari Karppinen as the principal auditor.

The evaluators of the UK Notified Body, involved in the approval process of our product, with whom agreement was reached on the approval path, apparently moved to other tasks possible related to Brexit. A new reviewer, appointed by Notified Body, suggested that the large animal study should have had one additional control group associated with evaluation of medicinal effect of bone protein exctract, i.e. classification of ARTEBONE. We would have been able to challenge this proposal by discussing with UK competent authorities controlling Notified Body, but it was no longer possible this year due to Brexit, because Notified Body was already registered in EU, Amsterdam. Therefore, there was no other option but to repeat the animal study. The animals were operated in August 2019 and the three-week follow-up results are expected to be completed in February 2020. The CE-mark application will be filed with these results and complete it later with 8 and 12 weeks results.

The subscription period for the directed share issue to Sweden expired June 30th 2019. On July 1th 2019 the Board of Directors approved the subscriptions and the subscribed shares were transferred to the book-entry account of subscribers on July 10th 2019. A total of 215 new shareholders subscribed for a total of 114 300 new shares. The share issue resulted in a dilution of approximately two percent in the number of shares and voting rights. The company's total number of shares is 5 204 820 after the registration (July 5th 2019) of new shares.

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 2020

The financial statement bulletin for January-December 2019 will be published on 20th March 2020,

at 9 am. Interim Report H1/2020 will be released in August 31th 2020 at 9 am.

In Oulu August 30, 2019
BBS-Bioactive Bone Substitutes Plc
Board of Directors

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Key media

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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 30th August 2019 at 12:00 am (UTC).

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-mark 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.

ATTACHMENTS:

Financial Statement 30th June 2019
Cash Flow Statement 30th June 2019
Statement of changes in equity

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