

**SUPPLEMENT TO BBS-BIOACTIVE BONE SUBSTITUTES PLC'S INVESTOR MEMORANDUM DATED
24th of NOVEMBER 2023**

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BBS-Bioactive Bone Substitutes Plc ("**BBS**" or the "**Company**") supplements the Company's investor memorandum dated 24th of November 2023 (the "**Investor Memorandum**") relating to its rights share issue with the information set out below. The information below shall be read together with the Investor Memorandum.

Supplements to the Investor Memorandum

The Investor Memorandum is supplemented with the following information:

1. On 25th of November 2023, the Company has announced in a press release that it has received confirmation from the Notified Body that the Company's quality system has received final approval and the official quality certificate has been delivered to the Company.

As a result of the supplement, the following amendments are made to the Investor Memorandum. Changed information is indicated by underlining or by ~~striking through~~ where applicable.

Section "Background and reason for the Offering and use of proceeds" in pages 6-7 of the Investor Memorandum is amended to read as follows:

Background and reason for the Offering and use of proceeds

BBS is applying for the CE marking for its first product, ARTEBONE® Paste bone implant. On 9th of March 2022, BBS submitted the CE marking application to the Notified Body in the Netherlands. The authorities' original estimate for the processing time was 8 to 12 months from the filing. Subsequently, the processing times have lengthened, as indicated by a survey published by Medtech Europe, such that approvals for new products are not being granted within the original target time framework of one year. The delays are typically due to the authorities being overburdened, in part because the new Medical Device Regulation (MDR) necessitates the re-approval of existing products as well. Due to delays in the processing of the CE marking application, the Company must seek bridge financing to secure its funding until the CE marking is obtained.

Despite the delays, ARTEBONE® Paste's product approval process has made good progress with no significant non-conformities being reported which could endanger the product's approval. In May 2023, the Company was informed of the particularly critical decision regarding product classification. ARTEBONE has been a new type of borderline case between medical devices and medicines, and the Company became a significant precedent from a regulatory point of view on how such products can overall be given approvals. This is also evidenced by the fact that BBS was even included as an example in the industry manual published in 2018 (Manual on borderline and classification in the community regulatory framework for medical devices, version 1.19 (04 2018)).

The first audit of the quality system was conducted in November 2022 and the following one in March 2023. On 2nd of November 2023, the Company announced that the relevant authority has delivered a certificate related to the quality system approval to the Company for review, which will be officially approved by the relevant body. Simultaneously the Company announced that according to the authorities the consultation with the Finnish Medicines Agency (FIMEA) will begin on 21st of November 2023, which will be one of the final phases of the CE marking process. The official product approval process is underway alongside the consultation. On 25th of November 2023, the Company has announced that it has received the final quality system certificate from the relevant authority.

The Company estimates that the CE marking application will be approved during the second quarter of year 2024. 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. Instead the main actual challenge is predicting the time it will take for the process, which the Company cannot entirely control, as the Notified Body makes decisions independently. In general, a medical device is granted approval if 1) the product meets the safety requirements (its use does not cause harm), and 2) the products therapeutic efficacy must be demonstrated for its intended purpose. Both of these aspects are tested and verified through animal tests and clinical trials during the product development phase, before the regulatory approval process is initiated. BBS's ARTEBONE® Paste has already cleared these stages. The final ongoing regulatory approval phase mainly consists of consultations with the Medicines Agency and the finalization of the Company's production and quality control processes, including test production batches.

The Company estimates that the net proceeds raised through the Offering will be used for executing the Company's business plan, strengthening working capital and investments as well as managing and repaying loans, including but not limited to the following items:

1. The primary purpose of the proceeds to be raised is the successful completion of the ongoing application process for the CE marking for the Company's bone implant ARTEBONE® Paste, ~~including the certification of the Company's quality system~~. The funds will also be used for product development, patent portfolio maintenance and production development as well as for the FDA approval application process to gain marketing authorisation for ARTEBONE® Paste on the US market.
2. To initiate the commercialisation of ARTEBONE® Paste, including sales and marketing asset recruitment and training, preparation of marketing materials as well as assessing and contacting initial potential customers.
3. Payment of principal instalments and interest of EUR 0.5 million in Business Finland loans that are due in the next 12 months.

The estimate of the usage of the proceeds presented above is based on the assumption that the Offering will be subscribed in full.

The estimated portions of the use of proceeds may differ depending on the amount of funds raised and the development of business operations. If the Offering is not subscribed in full, it may not be possible to carry out the planned actions in full, and cost-cutting measures will need to be introduced, which may delay the start of production, marketing and sales.

* MedTech Europe Survey report. <https://www.medtecheurope.org/wp-content/uploads/2022/07/medtech-europe-survey-report-analysing-the-availability-of-medical-devices-in-2022-in-connection-to-the-medical-device-regulation-implementation.pdf>

Section "CE marking process close to the finish line: The Company is approaching the commercial stage" in pages 9-10 of the Investor Memorandum is amended to read as follows:

CE marking process close to the finish line: The Company is approaching the commercial stage

For BBS to be able to commercialise its first product, ARTEBONE® Paste, the product must be granted a CE marking by the Notified Body. The Company filed the application on 9th of March 2022 and based on the currently available information BBS expects that the CE marking would be granted during the second quarter of 2024.

The CE marking process has two principal components: quality system approval and product approval.

Quality system approval

On 2nd of November 2023, the Company announced that the relevant authority has delivered a certificate related to the quality system approval to the Company for review, which will be officially approved by the relevant body. On 25th of November 2023, the Company has announced that it has received the final quality system certificate from the relevant authority.

Product approval

On 26th of May 2023, the Company announced that it had received information that the Notified Body has approved ARTEBONE® Paste's product classification as medical device. The product classification decision

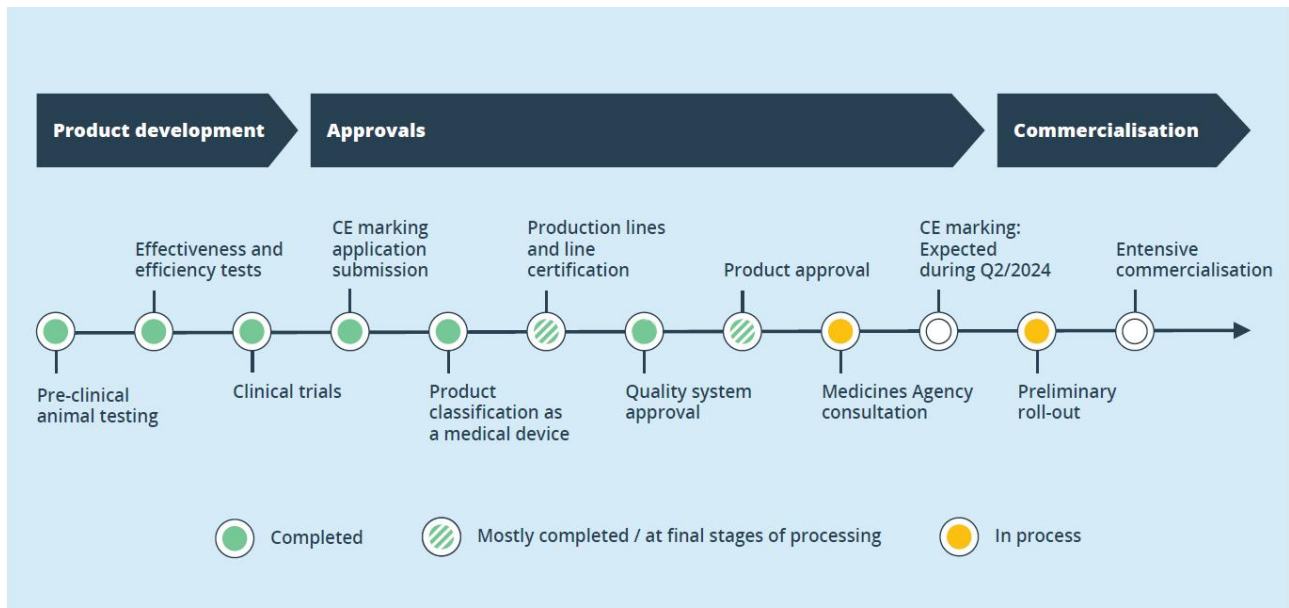
is a central part of the product approval process. It was particularly significant for the Company, as the decision ensured that the CE marking process for the Company's first product may proceed in accordance with the targeted simpler and more cost-effective administrative process. The granting of final product approval requires cooperation between the Notified Body and the medical agency handling the matter. On the 2nd of November 2023, the Company announced that according to the authorities the consultation with the Finnish Medicines Agency (FIMEA) would begin on 21st of November 2023 and is estimated to last approximately 3 - 7 months. During the final phases of the CE marking process, the Company also carries out test production batches required by the production and quality control processes, while at the same time, the Notified Body completes the remaining steps related to the CE marking approval.

Approval delayed due to the backlog in the official processes

Public statistics* indicate that the average processing time of CE applications by the authorities increased in 2022. This backlog was due to the new Medical Device Regulation, due to the new MDR-regulation, not only the new products must be registered but all products that were already on the market must also be re-registered.

* MedTech Europe Survey report. <https://www.medtecheurope.org/wp-content/uploads/2022/07/medtech-europe-survey-report-analysing-the-availability-of-medical-devices-in-2022-in-connection-to-the-medical-device-regulation-mdr-implementation.pdf>

Stage	Action	Status
Product development	Pre-clinical animal testing	Completed
	Effectiveness and efficiency tests	Completed
	Clinical trials	Completed
CE marking	CE marking application submission	Completed
	Quality system approval	Mostly completed Completed
	1st audit	Completed
	2nd audit	Completed
	Additional audit	Completed
	Additional measures	Plan approved
	Product approval	At the final stages of processing
	Product classification	Completed
	Medicines Agency consultation	Begins 21st of November
	Production lines and line certification	Mostly completed
	CE marking	Expected during Q2/2024
Commercialisation	Preliminary roll-out	Initiated
	Extensive commercialisation	In preparation



The risk description below in pages 19-20 of the Investor Memorandum is amended to read as follows:

There are risks involved with the granting of a CE marking and FDA approval for the BBS product which may cause significant additional costs and delays

The Company submitted an application for a CE marking for ARTEBONE® Paste on 9th of March 2022. To the best of the Company's knowledge, the application is in compliance with the relevant official requirements. Because granting a CE marking is at the discretion of the authorities and because there is scope for interpretation in the official requirements, it is possible that the Company has interpreted them differently than the authority deciding on the matter. An interpretation by the authority differing from that of the Company may lead to delays in the approval process and additional requirements.

The CE marking process has two principal components: quality system approval and product approval. The Notified Body has made two official audits for the purpose of approving the BBS quality system. During the second audit in March 2023, the representatives of the Notified Body reviewed the detailed product documentation and production processes more closely. On 2nd of November 2023, the Company announced that the relevant authority has delivered a certificate related to the quality system approval to the Company for review, which will be officially approved by the relevant body. On 25th of November 2023, the Company has announced that it has received the final quality system certificate from the relevant authority.

On 26th of May 2023, the Company announced that it had received information that the Notified Body has approved ARTEBONE® Paste's product classification as medical device. The product classification decision is a part of the product approval process. It was particularly significant for the Company, as the decision ensured that the CE marking process for the Company's first product may proceed in accordance with the targeted simpler and more cost-effective administrative process. The granting of the final product approval requires cooperation between the Notified Body and the medical agency handling the matter.

If the authority does not accept the CE marking application submitted by the Company on 9th of March 2022, the Company may be obliged to change its operations and/or to conduct further testing, which may result in additional costs. Delays in the granting of the CE marking will delay the bringing of ARTEBONE® Paste to market, which in turn will delay the generating of the turnover expected from sales of the product, and the Company will continue to operate at a loss. As long as the Company continues operating at a loss, it will need additional funding to be able to continue and develop its operations. If the needed additional funding is not obtained, the Company will not be able to develop its operations as planned and may end up insolvent. If it should happen that the CE marking application for ARTEBONE® Paste submitted by the Company were rejected or the granting of the CE marking were delayed from what was anticipated by the Company, for instance because of emerging delays in the validation process, this may have a material negative effect on the Company's business operations, financial performance, financial position and/or securities value.

The Company plans to continue preparations for the FDA 510(k) approval process for ARTEBONE® Paste after the CE marking is granted. Even if the CE marking application for ARTEBONE® Paste were approved, there is significant uncertainty about the FDA approval for ARTEBONE® Paste. Because the US market is one of the most important markets for medical devices, delays in the FDA approval process or failure to obtain FDA approval for ARTEBONE® Paste at all may have a material negative effect on the Company's business operations, financial performance, financial position and/or securities value.

2. In addition to the previously announced subscription undertakings, the Company has received subscription undertakings in the amount of EUR 162,000 from Panvest Oy and EUR 10,000 from CEO Juliusz Rakowski.

As a result of the supplement, the following amendments are made to the Investor Memorandum. Changed information is indicated by underlining where applicable.

The risk description below in pages 23-24 of the Investor Memorandum is amended to read as follows:

The Offering may fail to raise the proposed funds in full, and if the funds raised with the Offering are substantially less than expected, this will affect the Company's ability to use the proceeds as planned

There is no certainty that the Offering will be fully subscribed. The Company has received subscription undertakings from existing shareholders and two new investors to a total of about EUR 0.93 million. Thus, the parties who have submitted subscription undertakings have committed to subscribe a total of about 35.3 % of the Offering (see section "Terms and conditions of the Offering – Subscription undertakings" of the Investor Memorandum). The Company has neither received nor requested collateral from parties who have committed to subscribing Offer Shares in the Offering on the basis of their subscription undertakings. Although the Company trusts the parties from whom it has received subscription undertakings, there is no certainty that all the parties submitting subscription undertakings will meet their obligations to the Company. If not all parties submitting subscription undertakings do not fulfil their obligations towards the Company, the Company may be obliged to take legal action, which will cause costs and delays in receiving these payments. In such a scenario, the Company may also not gain as much funds from the Offering as would be the case if all the aforementioned parties were to fulfil their obligations according to their agreements.

If a significantly lower amount of funds is raised with the Offering than expected, this would affect the Company's ability to use the proceeds in a planned manner, which may cause delays in commencement of production, marketing and sales. For this reason, the market price of the Company's shares could drop below the Subscription Price of the Offering. In these conditions, investors who have participated in the Offering by subscribing Offer Shares, may suffer a direct unrealised loss as a result of their investment.

Section "Subscription undertakings" in page 26 of the Investor Memorandum is amended to read as follows:

Subscription undertakings

Certain current shareholders of the Company and two new investors mentioned below have provided subscription undertakings, on the basis of which they have committed to subscribe for approximately 35.3 percent of the Offer Shares offered in the Offering, i.e. they have committed to participate in the Offering with 0.93 million euros. The Company has received the following subscription undertakings to subscribe for Offer Shares in connection with the Offering:

Shareholder subscribing for Offer Shares	Subscription undertaking (shares)	Subscription undertaking (EUR)
Municipality of Reisjärvi	831,000	332,400
Finha Capital Oy	700,000	280,000
<u>Panvest Oy</u>	<u>405,000</u>	<u>162,000</u>
Muoraus ja Rappaus Saarimaa Oy	127,500	51,000
Riverfort Global Opportunities PCC Limited	125,000	50,000
Pekka Jalovaara	50,000	20,000
Jyrki Halonen	35,000	14,000
Jarmo Halonen	25,000	10,000

<u>Juliusz Rakowski</u>	<u>25,000</u>	<u>10,000</u>
Total	<u>2,323,500</u>	<u>929,400</u>

The Company has not received or requested collaterals from the parties that have committed to subscribe for the Offer Shares in the Offering on the basis of subscription undertakings.

Availability of certain documents

A copy of this supplement will be kept available in electronic form on the Company's website <http://bbs-artebone.fi/share-issue-2023-11>, and copies of them may be viewed at the Company's main offices at Kiviharjunlenkki 6, FI-901220 Oulu during normal office hours.