BBS-Bioactive Bone Substitutes Plc: BBS arranges a rights offering of approximately maximum EUR 2.4 million

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BBS arranges a rights offering of approximately maximum EUR 2.4 million

Based on authorization granted by the Annual General Meeting on June 13, 2024 the Board of Directors of BBS-Bioactive Bone Substitutes Plc ("BBS" or the "Company") has decided to arrange a rights offering totaling approximately EUR 2.4 million (the "Offering"). The Offering consists of a maximum of 8,298,870 new shares (the "Offer Shares").

Summary

- Approximately maximum of EUR 2.4 million before transaction costs may be raised in the Offering if fully subscribed.
- BBS will give all its shareholders registered in BBS's shareholder register maintained by Euroclear Finland Ltd ("Euroclear Finland") one (1) book-entry subscription right (the "Subscription Right") for each share held on the Offering record date. Each five (5) Subscription Rights entitles the holder to subscribe for two (2) Offer Shares.
- The record date for the Offering will be August 28, 2024 with the last day of trading including the Subscription Rights on August 26, 2024 and the first day of trading excluding the Subscription Rights on August 27, 2024.
- The subscription price is EUR 0.29 per Offer Share. The subscription period for the Offer Shares (the "Subscription Period") will commence on September 2, 2024 at 10:00 AM Finnish time, and it is expected to end on September 20, 2024 at 16:00 PM Finnish time.
- Net proceeds from the Offering will be used inter alia for successful completion of the ongoing CE marking application process for BBS' bone implant ARTEBONE® Paste, for initiating the commercialisation of ARTEBONE® Paste and for paying the loan repayments and interest.

Reasons for the Offering and use of proceeds

BBS is applying for the CE marking for its first product. ARTEBONE® has had a complex and challenging approval process. It is a new and innovative bone substitute, which is always considered risky from the authorities' perspective, and proving its functionality is also more laborious than for a simpler product. At the beginning of product development, the authority classified ARTEBONE® as a medicinal product due to its bone protein extract content, so product development was advanced as a medicinal product for about 5 years. However, it turned out that obtaining funding for a Finnish company located in a remote area for drug development was challenging, and hundreds of millions of

extra funds would have been needed. Furthermore, it became apparent that ARTEBONE® might be approved as a medical device. Numerous negotiations were held with the authorities on this issue, which eventually accepted this alternative product registration route. However, the authorities did not have guidance for classifying a product combining a medical device and a drug. The aforementioned classification guidance was only received in 2018 from the European Commission concerning products on the borderline between a medical device and a drug (Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices, Version 1.19 (04-2018) 4.22), where ARTEBONE® is described as an example of a combination of osteoconductive ceramic (TCP) and osteoinductive medicinal substance. It also describes how ARTEBONE® can be approved in the medical device class III, which is the route the Company has followed in registration.

In March 2022, the background work was completed, and the CE mark application documentation (European marketing authorization application) was submitted to the medical device evaluator (BSI) located in Amsterdam. The submission of the marketing authorization application took place at a time when there had been a significant change in the approval bureaucracy with the new regulation MDR 2017/745 for medical devices coming into force. All old products also had to seek approval under the new regulation, causing massive backlogs for the authorities, also prolonging the approval process for ARTEBONE®. The official classification decision was received in May 2023, confirming the Company's vision of ARTEBONE®'s product classification in medical device class III.

The first phase of the ISO 13485 quality management system inspection, which covers product manufacturing and ensures patient safety, i.e., the pre-inspection, began in November 2022. A separate microbiological inspection was held in February 2023, and the final inspection of the microbiological section was conducted in January 2024. Extensive phase 2 inspections began in March 2023, and the final inspection was conducted in August 2023. Fimea's GMP inspection ("Good Manufacturing Practice"; a standard compliant with pharmaceutical industry quality requirements) took place in May 2023.

The quality system certificate was obtained in November 2023. A periodic inspection of Fimea's GMP certificate, i.e., the pharmaceutical manufacturing license, was conducted in June 2023. The certificates require continuous periodic inspections every 1–3 years."

ARTEBONE® contains all three levels of product approval difficulty; it is new and innovative, it contains an animal-derived component, and it also includes a medicinal component. Therefore, the approval process is significantly more challenging and time-consuming than for a simple medical product. For example, the approval of ARTEBONE® requires an inspection by the medicinal authority and an evaluation of the clinical trial for the medicinal component, which began in November 2023. Additionally, the EDQM (European Directorate for the Quality of Medicines & HealthCare) conducts an assessment of the safety and benefit of the animal-derived component.

Currently, the authorities and BBS are working on the evaluation of the technical documents. The Company, in the opinion of its management, has been able to meet all the authorities' requirements regarding the product's functionality and safety, both in animal tests and in the clinical trial. The Company expects the CE mark soon, once the authority has completed its work. The Company cannot provide an exact timeline, as the authority takes its time and does not provide schedule forecasts.

The competitive situation for ARTEBONE® remains good. There is only one competitor on the market that applies a similar innovation, which includes a protein component in addition to TCP. This setup was the starting point for the development of ARTEBONE®. The Company aims to create a bone substitute that closely resembles natural bone, which is achieved in the ARTEBONE® product. Unlike all competitors, the ARTEBONE® product combines both an osteoinductive component, which initiates bone formation, and an osteoconductive component, which serves as a platform for bone formation. The majority of competing products contain only one component.

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

1. The principal purpose of the proceeds to be raised is the successful completion of the application process for a CE marking for the BBS bone implant ARTEBONE® Paste. The funds will also be used for product development, patent portfolio maintenance and production development, and also for the FDA approval process for obtaining marketing authorisation for ARTEBONE® Paste on the US market. The application process for FDA approval will continue after the completion of CE marking approval.
2. For initiating 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. For payment of principal instalments and interest of EUR 0.7 million in loans that are due in the next 8 months.

The estimate of how the proceeds are intended to be used 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 in turn may delay the start of production, marketing and sales.

Terms of the Offering

- The Company will offer maximum of 8,298,870 Offer Shares for subscription in accordance with the shareholders' preferential subscription right. The main terms for the Offering are presented below.
- All shareholders registered in BBS's shareholder register maintained by Euroclear Finland will be given one (1) book-entry Subscription Right for each share held in the Company on the Offering record date August 28, 2024. Each five (5) Subscription Rights entitles the holder to subscribe for two (2) Offer Shares.
- The Subscription Rights will be registered in the shareholders' book-entry accounts in the book-entry system maintained by Euroclear Finland approximately on August 29, 2024.
- The Subscription Rights registered with Euroclear Finland will be freely transferable and will be traded on First North Growth Market Finland ("First North Finland") between September 2, 2024 and September 17, 2024.

- After the subscription, temporary shares corresponding to the Offer Shares subscribed for based on the Subscription Rights (the "Temporary Shares") will be entered into the subscriber's book-entry account.
- Trading in the Temporary Shares is estimated to begin on First North Finland September 2, 2024.
- The Temporary Shares will be combined with the Company's current shares after the Offer Shares have been registered into the Trade Register, which is estimated to take place on approximately September 30, 2024.

Investor Memorandum and the Basic Information Document

In connection with the Offering, the Company has prepared this Investor Memorandum ("Investor Memorandum") as well as a Basic Information Document in accordance with Chapter 3, Section 2 of the Finnish Securities Markets Act (746/2012, as amended) ("Basic Information Document") with corresponding attachments, both of which are available on the Company's website: https://www.bbs-artebone.fi/investors/share-issue-2024-9/

Indicative timetable

August 26, 2024	Resolution regarding the Offering by the Board of Directors
August 26, 2024	The Investor Memorandum and the Basic Information Document are published
September 2, 2024	Subscription Period begins (estimate)
September 2, 2024	Trading in Temporary Shares and Subscription Rights begins on First North Finland (estimate)
September 17, 2024	Last day of trading on First North Finland in Subscription Rights (estimate)
September 20, 2024	Subscription Period ends unless extended (estimate)
September 24, 2024	Outcome of the Offering announced (estimate)
September 30, 2024	Last day of trading on First North Finland in Temporary Shares (estimate)
September 30, 2024	Offer Shares delivered to the book-entry accounts of subscribers (estimate)
October 1, 2024	Trading in Offer Shares begins together with Company's existing shares on First North Finland (estimate)

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Advisers

Aalto Capital Partners Oy is acting as financial advisor to the Company in the Offering. Smartius Oy is acting as the legal adviser to the Company on aspects of the Offering related to the Finnish law.

BBS-BIOACTIVE BONE SUBSTITUTES PLC

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BBS in brief
BBS -Bioactive Bone Substitutes Plc is an orthobiology company that started its operations in 2003. We have developed a new product for the treatment of complex bone fractures and bone healing issues. Our goal is to provide next-generation medical products for the treatment of bone injuries in orthopedic surgery. In the pharmaceutical industry, the development and research work require perseverance and courage to innovate. We have a track record of over 20 years in this field. Our company is characterized by expertise, innovation, and dedicated employees who are passionate about their work. Our first developed product, ARTEBONE® Paste, is in the final stages of the CE marking process to enable its commercialization in the EU market. We are based in Oulu with a medical manufacturing facility in Reisjärvi, holding a manufacturing license. The company's headquarters are in Oulu, and we employ over 20 people.

BBS has been listed on Nasdaq First North Growth Market Finland since February 2018.

More information: www.bbs-artebone.fi