BBS-Bioactive Bone Substitutes Plc – Insider information: BBS updates its action plans

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Insider information: BBS updates its action plans

BBS-Bioactive Bone Substitutes Plc updates its action plans in a situation where the processing of the Company's Artebone® Paste product's European application for certification was refused by the Notified Body (BSI).The refusal was based on that the clinical trial conducted by BBS, which was intended to be supplemented by a Post Market Clinical Follow-up study after CE marking approval, was conducted according to MDD rules. The supervisory authority required compliance with the new MDR regulations, which came into effect after the completion of the clinical trial, and which require a larger number of patients to demonstrate statistical evidence. The Company can submit a new CE marking application after increasing the number of patients in accordance with MDR requirements. The Company has made a plan and started preparations for conducting the supplementary clinical trial.

In the current situation, the Board of BBS has also decided to start evaluations to secure the Company's financial situation and operations. The Company has entered into a cooperation agreement with ConAlliance GmbH (https://www.conalliance.com/), which covers all possible options and actions related to the Company's additional financing and strategic industrial cooperation options.

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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