ESPI RAPORT 13/2026 | 21 April 2026 | Initiation of U.S. collaboration for clinical studies to support FDA registration of BACTEROMIC with UNI FAST panel

Further to Current Report No. 8/2026 regarding the update of objectives for the BACTEROMIC project for 2026–2027, the Management Board of Scope Fluidics S.A. ("**Scope**") announces that Bacteromic sp. z o.o. ("**Bacteromic**") has initiated collaboration with a U.S.-based clinical research centre (the "**Centre**") The Centre will conduct clinical performance studies to support the U.S. Food and Drug Administration (FDA) submission (the "**Studies**") for the BACTEROMIC system equipped with an expanded UNI FAST panel (i.e. up to 52 antibiotics). The initiation of this U.S. collaboration for clinical studies represents a significant milestone in the FDA regulatory pathway.

Presentation of clinical study findings is required for filing an FDA marketing application (the "submission"). In accordance with FDA requirements, Bacteromic plans to conduct the Studies both at clinical sites in the United States and in its in-house laboratory. The submission will additionally require completion of analytical performance testing and precision (reproducibility/repeatability) studies of the system. These analytical and reproducibility assessments will also be performed at U.S. sites and in Bacteromic's internal laboratory.

Legal basis: Article 17(1) MAR – Inside information