

ASX Announcement



Medibio Limited – 18 May 2022

U.S. FDA Confirms a DSM-V Diagnostic Method for Medibio’s Final Depression Validation Trial

Melbourne, Australia and Minneapolis, USA – 18 May 2022: Medibio Limited (MEB or the Company) (ASX: MEB) (OTCPINK: MDBIF): Following the March Quarterly Report, Medibio is pleased to announce that a DSM-V¹ diagnosis will be included as a primary comparator for the purposes of assessing the efficacy of its depression algorithms, MEB-001.

Medibio’s clinical team proposed the International Neuropsychiatric Interview (MINI) as a diagnostic tool to satisfy the FDA’s request whilst minimizing the burden of conduct for the validation trial. The FDA has confirmed that the MINI can be used to support the trial clinician diagnosis.

Claude Solitario, Managing Director of Medibio said: *“Medibio welcomes the confirmation by the FDA for MEB-001 to be compared to a mental health diagnosis. This will significantly enhance our De Novo application and, depending upon the results of the trial, may present an opportunity to upgrade MEB-001’s Indication for Use from a screening tool to a screening/diagnostic tool. The request by the FDA to add a clinical diagnosis as a primary comparator to MEB-001 will result in the technology being one major step closer to recognition as a diagnostic tool, a mission Medibio has been working towards for many years, and one that would represent a groundbreaking development in the diagnosis, treatment and management of mental health conditions.”*

– ENDS –

This announcement is authorized for release to the market by the Board of Directors of Medibio Limited

About Medibio Limited

Medibio (ASX: MEB) (OTCPINK: MDBIF) is a health technology company pioneering the use of objective measures to aid in the early detection and screening of mental health conditions. Through their Corporate Health product, the Company offers mental well-being solutions for businesses and are also developing products to serve the healthcare provider market. The company was founded in Australia, with offices located in Melbourne (Vic) and U.S. offices in Minneapolis, MN. Medibio is listed on the Australian Securities Exchange Ltd and trades on the OTC Pink Open Market. Investors can find additional information on www.otcmarkets.com and www.asx.com.au.

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¹ Diagnostic and Statistical Manual of Mental Disorders – Fifth Edition