

ASX Announcement

Medibio Limited – 3 December 2020



Update on Breakthrough Device Program

Melbourne, Australia and Minneapolis, MN – 3 December 2020: Medibio Limited (“MEB”, “Medibio” or the “Company”)(ASX: MEB)(OTCPINK: MDBIF), a mental health technology company pioneering the use of objective measures to aid in the early detection and screening of mental health conditions provides the following update in relation to its request to the U.S. Food and Drug Administration (FDA) for Breakthrough Device Designation for the Company’s depression diagnostic software, MEB-001.

Medibio has received notification from the FDA that its request for Breakthrough Designation has not been granted. However, they have asked for further information and clarification of certain issues and invited the Company to discuss the decision with them to resolve any potential disputes and the right of appeal, should a resolution not be found.

The FDA Breakthrough Devices Program provides a process for companies to address disagreements with the FDA’s decision, through discussion with the staff who reviewed the submission, and where that fails to resolve the disagreement, a request for supervisory review, and the filing of an appeal.

After consulting with its regulatory experts, Medibio has requested a meeting with the FDA to discuss the issues raised in the notification letter. The Company will await the outcome of that meeting before deciding whether to pursue further supervisory review or an appeal of the FDA’s decision.

The FDA’s decision to deny Breakthrough Device Designation has no impact on the progress of the MEB-001 trial.

Medibio is currently undertaking a trial to validate MEB-001 as a medical software device. The trial is ongoing in Minnesota (Lakelands Sleep Centre) and Ohio (MedBridge Healthcare). The data from the trial will form the basis of an FDA De Novo application.

MEB-001 uses artificial intelligence, deep learning algorithms and neural network methodology to identify biological patterns and markers in overnight heart rate activity as an objective, data-driven method to assist in the diagnosis of depression in patients that suffer from sleep disturbance.

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

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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.

Medibio Investor and Media Enquiries:

Arthur Chan

WE Communications

T: +61 (0) 404 369 388

WE-AUMedibio@we-worldwide.com