

ASX Announcement

Medibio Limited – 27 February 2023



Medibio Lodges Breakthrough Device Designation with FDA

Melbourne, Australia and Minneapolis, MN – 27 February 2023: Medibio Limited (“MEB” or “Medibio”) (ASX: MEB) (OTCPINK: MDBIF) is pleased to provide the following update and advises that it has met a major strategic milestone in lodging its Sleep Analysis of Depressive Burden study (MEB-001) algorithm under the Breakthrough Device Designation (“BDD”) with the FDA.

The achievement for the Company to lodge the BDD submission with the FDA for the Sleep Analysis of Depressive Burden study (MEB-001) is a great milestone and it is expected to hear back from the FDA with initial feedback within 60 days from the submission.

The BDD acceptance will ensure a much closer working relationship with the FDA for the approval of the MEB-001 product. MEB-001 Sleep Analysis of Depressive Burden looking at the biomarkers and physiologic parameters of current major depressive disorder is a new approach to the recognition of depression.

In commenting on the submission, David Trimboli, Non-Executive Chair of Medibio Limited said: *“We are pleased to have finalised the MEB-001 BDD submission. This represents the first step for the new Management and Board of MEB in pushing for FDA approval and continuing to develop our core MEB-001 technology”.*

– ENDS –

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

For Further information:

David Trimboli
Non-Executive Chair
T: +61 3 9692 7222

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.