

# ASX Announcement



21 July 2023

## Update on Breakthrough Device Designation with US FDA

**Perth, Australia, and Minneapolis, USA: Medibio Limited (MEB or the Company)** (ASX: MEB) (OTCPINK: MDBIF) advises that following an initial submission (refer ASX announcement: 27 February 2023), the US Food and Drug Administration (FDA) have notified Medibio that MEB-001 in its current form does not meet the criteria for designation as a Breakthrough Device.

**This decision does not affect the Company's current De Novo regulatory pathway, which is actively being pursued in collaboration with the Company's Phase 1 and Phase 2 trial initiatives.**

Throughout the BDD submission process, the Company has gained valuable feedback from the FDA which will be reviewed extensively in connection with the ongoing progression of its technology through the De Novo regulatory pathway.

Medibio remains on track with its trial initiatives and results from these will provide the requisite data to inform the Company's continued engagement with the FDA. Medibio expects to schedule a pre-submission meeting with the regulatory body during Q4 CY2023, which will provide a clear timeframe on the regulatory approval process.

Medibio is encouraged by its work to date, which has provided valuable data for the ongoing calibration of its proprietary algorithm and the basis for ongoing trial initiatives.

### Management commentary:

**CEO Dr Tom Young said:** *"Throughout the BDD submission process, we have gained very valuable feedback from the FDA on MEB-001 and remained in open dialogue with the regulator. This process will directly inform our ongoing clinical trial initiatives moving forward, as well as the data presented in our pre-submission meeting. Operationally, the Company continues to make very pleasing progress and we look forward to providing updates to shareholders as they materialise."*

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

**ENDS**

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### About Medibio Limited

Medibio (ASX: MEB) (OTCPINK: MDBIF) is a mental 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 Perth (Western Australia) and Minneapolis (MN, USA). Medibio is listed on the Australian Securities Exchange Ltd and trades on the OTCQB Venture Market. Investors can find additional information on [www.otcmarkets.com](http://www.otcmarkets.com) and [www.asx.com.au](http://www.asx.com.au).