

ASX Announcement

Medibio Limited – 29 December 2020



US FDA advises further data needed for MEBsleep approval

Melbourne, Australia and Minneapolis, MN – 29th December 2020: Medibio Limited (MEB or the Company) (ASX: MEB)(OTCPINK: MDBIF), announces that the US Food and Drug Administration (FDA) has advised it will require a larger sample of clinical data, better reflecting the proposed intended use population, in order for it to be considered substantially equivalent in relation to its 510(k) application.

The FDA has provided a detailed pathway as to how Medibio may achieve approval for MEBsleep and they have invited the company to discuss the additional steps required for approval. The Company intends to meet with the FDA as soon as practical to discuss the additional data required for approval in order to determine the next steps for MEBsleep.

Whilst regulatory approval is not required for MEBsleep's primary purpose as an integral part of the depressive burden software device MEB-001, the Company believes MEBsleep is of value to potential partners for uses independent of MEB-001.

Claude Solitario, Managing Director of Medibio, commented:

"We intend to meet with the regulator as soon as practical to understand the additional data required for MEBsleep's 510(k) approval. We will then assess the merits of a re-submission. We are also exploring other avenues for the commercialization of MEBsleep that do not require regulatory approval, such as the pharmaceutical research market pursuant to Investigational Device Exemptions (IDE) regulations; and other partnership opportunities".

"It is important to note that this program has not affected the progress of the depressive burden trial which is Medibio's primary objective and from which we will not deviate".

– ENDS –

This announcement is authorised 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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