ASX Announcement

Medibio Limited – 29 April 2021

Medibio to resubmit FDA 510(k) application for its sleep staging software, MEBsleep

Melbourne, Australia and Minneapolis, Minnesota – 29 April 2021: Medibio Limited (**Medibio, MEB** or the **Company**) (ASX: MEB) (OTCPINK: MDBIF) announces that it has secured a pre-submission meeting with the US Food and Drug Administration (FDA) on the 1st July 2021, regarding a new 510(k) application for its sleep staging software, MEBsleep.

Medibio submitted a 510(k) application for MEBsleep in April 2020. In December 2020, the FDA informed Medibio that it required clinical data that better reflected the proposed intended use population and provided a detailed pathway as to how Medibio may achieve approval for MEBsleep.

Following that guidance, Medibio commissioned an independent, in-depth review of its MEBsleep technology by the well-known and respected regulatory law firm, DuVal & Associates.

As a result of the FDA guidance and subsequent extensive consultation with DuVal & Associates, Medibio has designed a new prospective, multicenter clinical trial to address the FDA issues raised and to inform its new 510(k) application. Access to sleep clinics pursuant to Medibio's agreement with MedBridge Healthcare, which operates 130 sleep clinics across the USA, will greatly assist in completing the trial as quickly as possible. It is anticipated that, barring any unforeseen circumstances or delays, the trial can be completed, and the new application submitted, within 6 to 8 weeks from commencement.

The purpose of the pre-submission meeting with the FDA is to agree on, amongst other things, the trial design, its objectives and the number and diversification of the patient population.

MEBsleep forms a substantial part of the suite of algorithms used to identify depressive burden, known as MEB-001 (i.e., MEB-001 consists of MEBsleep algorithms with overlaying overnight resting heart rate and heart rate variability analysis) It is noteworthy from a cost-efficiency standpoint that the patients participating in the MEBsleep trial will also be eligible for the depressive burden trial (MEB-001).

Medibio will provide further details following the pre-submission meeting with the FDA.

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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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