ASX Announcement

Medibio Limited – 2 October 2020

Medibio Submits Request For FDA Breakthrough Device Designation

Melbourne, Australia and Minneapolis, MN – 2 October 2020: Medibio Limited (**MEB** 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, announces today that it has submitted with the US Food and Drug Administration (FDA) a Designation Request for Breakthrough Device for its depressive burden software medical device MEB-001.

The submission occurs concurrently to Medibio's ongoing clinical trial as devices subject to requests for De Novo designation are also eligible for Breakthrough Device Designation.

The FDA's Breakthrough Devices Program supports accelerated development, assessment, and review of devices that promise a more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, and meet at least one of the following criteria: (a) Represents Breakthrough Technology; (b) No Approved or Cleared Alternatives Exist; (c) Offers Significant Advantages over Existing Approved or Cleared Alternatives; or (d) Device Availability is in the Best Interest of Patients.

Breakthrough Device Designation provides additional opportunities to interact with FDA experts and senior management prior to its submission for approval; and fast-tracks the FDA's review process to reduce time-to-market for qualified devices. The FDA typically communicates its decision to grant or deny Breakthrough Device Designation within 60 calendar days of receiving the request.

Chief Medical Officer of Medibio Ltd, Dr Archie Defillo says: *"Depression is one of the most common mental health conditions in the general population. Fifty three percent of adults in the United States have reported that their mental health has been negatively impacted by the COVID-19 pandemic*[1]*. The need for an objective mental health tool has never been greater."*

Depression is a known and robust risk factor for self-harm behaviour and death by suicide. The global annual mortality rate from suicide has been estimated by the World Health Organization to be 10.7 per 100,000 individuals, with variations across age groups and countries.

A major barrier to effective treatment for depression is inaccurate and/or inadequate diagnosis, which in turn contributes to its recurrence. Significantly, under-detection of depression increases the likelihood that it will result in a life-threatening disorder. Only fifty percent of patients with depression who are seen in the primary care setting will be accurately diagnosed, and of these, fewer than 10% will be appropriately treated.

Currently, screening is often conducted through **subjective** self-report questionnaires, which introduce multiple difficulties and biases into the screening. MEB-001 provides an **objective** measure of depressive burden, overcoming multiple difficulties and biases of self-report questionnaires.

[1] N Panchal, R Kamal, K Orgera, C cox, R Garfield, L Hamel, C Muñana, P Chimdambaram. The Implications of COVID-19 for Mental Health and Substance Use. Coronavirus – Covid 19. On-line Publication, August 2020.

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MEB-001 is a software-only medical device that analyses physiological signals, specifically electroencephalogram (EEG) and electrocardiogram (ECG), obtained from polysomnography (PSG). It automatically scores sleep-study results, including the staging of sleep, and autonomic modulation throughout sleep stages to discriminate the presence of depressive burden.

There are no other FDA-approved or cleared alternatives in the US market with this principle of operation.

– 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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