ASX Announcement

Medibio Limited – 9 November 2018

Medibio Provides Update on FDA Process

Sydney, Australia and Minneapolis, MN USA – 9 November 2018: Medibio Limited (**MEB** or the **Company**) (ASX: MEB) (OTCQB: MDBIF), a mental health technology company, today provides an update regarding the current De Novo submission and forward regulatory strategy. The company intends to pursue a parallel FDA premarket submission process, known as 510k clearance, in addition to the De Novo application. This is a more common path and offers a second route to the U.S. marketplace. We continue to expect FDA clearance and commercialisation next year.

As previously announced, Medibio submitted a De Novo application to the U.S. Food and Drug Administration (FDA) for our Clinical Decision Support System in July. We have now received the FDA's response to that submission, which requests clarification on 11 key points. This includes study methodology, intent of use, labelling and cybersecurity. "This is an expected and complex process when submitting a very innovative technology, as is the case with our product," said David B. Kaysen, Medibio's recently appointed CEO and Managing Director. "Our team has begun the process of gathering the required information to provide the FDA a detailed response, within their designated timeframe of up to 180 days. It is likely FDA will have further questions at that time. We remain focused on moving this De Novo process through the FDA system."

The De Novo application will require time and focus. Parallel to that effort, Medibio will concentrate on reviewing and achieving other regulatory avenues for one or more current modules, which address various mental health disorders. Kaysen goes on to say, "Based on this approach, we believe we are in a position to submit one or more 510k application(s) to the FDA. The 510k process is a more common route, which should provide us with FDA clearance for specific 510k pipeline products within the first four months of 2019."

While the De Novo application will take longer than originally anticipated, the full Medibio team will immediately pursue 510K application(s), while continuing to move through the De Novo process with the FDA. The team continues to believe that we will achieve a regulatory pathway to FDA clearance followed by commercialisation in 2019.

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About Medibio Limited
Medibio (ASX: MEB) (OTCQB: MDBIF) is a mental health technology company that has pioneered the use of objective digital biomarkers to assist in the screening, diagnosing, monitoring and management of depression and other mental health conditions. The company was founded in Australia, with offices located in Melbourne (Vic), Perth (WA) and U.S. offices in Minneapolis, MN. 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 and www.asx.com.au.

Further Information:

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