ASX Market Update

Medibio Limited (ASX: MEB) 1 April 2016

Medibio Completes Successful Pre-Submission Meeting with the US FDA

Medibio Ltd (**MEB** or the **Company**) is pleased to announce a positive Pre-Submission meeting with the United States Food and Drug Administration (FDA) on its proposed diagnostic for depression. It confirmed the proposed regulatory pathway of Medibio's depression test with the FDA. In addition, Medibio received confirmation from the FDA regarding the Company's proposed, indications for use, clinical study protocols, and data requirements.

The FDA has confirmed (based on the information provided in Medibio's Pre-Submission dossier):

1. The Medibio Depression Algorithm is eligible for the de novo regulatory pathway.
2. The FDA expressed no significant concerns with the proposed indications for use
3. Medibio's proposed Level of Concern for its Depression Algorithm is acceptable to the FDA.

Dr Matt Mesnik, Medibio's Chief Medical Officer commented: *"We were pleased with the high level of engagement from the FDA and the collaborative nature of the meeting. The confirmation of our regulatory pathway is an important milestone for the Company".*

Background

de novo Pathway - The *de novo* pathway was designed for innovative medical devices (ie, those without predicate devices) where controls provide a reasonable assurance of safety and effectiveness. The *de novo* process leads to a Class I, or in Medibio's case, a Class II classification. It has a 120-day review cycle compared with a 90-day review period for a 510(k).

Level of Concern - the FDA recommends submissions state the Level of Concern determined for a Software Device. The Level of Concern is based on how the operation of the software associated with device function affects the patient or operator. The extent of the documentation required in an FDA a premarket submission depends on the device's Level of Concern.

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