ASX Announcement

Medibio Limited – 19 March 2020

FDA STRATEGY UPDATE

- **Sleep staging algorithm "STAGER" currently showing an overall accuracy of 80%.**
- **Significantly faster processing time compared to human raters currently considered gold standard.**
- **On track for 510K submission early in the June quarter of 2020.**

Melbourne, Australia and Minneapolis, MN – 19 March 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, is pleased to announce that key evaluation milestones of its sleep algorithm "STAGER" have completed successfully.

STAGER forms a part of our depressive burden development platform known as MEB-001; however, we believe it has commercial value in itself. Currently, the identification of sleep stages is performed manually by certified sleep technicians. This is time consuming, costly and requires expertise. STAGER presents an opportunity for sleep technicians and doctors to improve patient care and/or serve larger patient populations without adding to their workload. This is particularly relevant as sleep analysis transitions from hospital outpatient departments and freestanding sleep clinics to home sleep testing.

Stager's unique selling proposition is its speed and accuracy. It differentiates itself from other sleep diagnostic systems in the following areas:

- Utilizes EEG and ECG to automatically score sleep study results including sleep staging and HRV during sleep stages;
- Saves time with scoring and analysis of up to 100 files analyzed simultaneously;
- Equal or better analysis accuracy than human raters; and hence
- Increase in laboratory volume and decreased backlog for studies that need to be scored by human raters.

Medibio will seek collaborations that will facilitate entry into its initial target market of research and academic institutions, followed by sleep laboratories. The revenue model will centre around a master license for 1 user with the option of additional users, followed by a price per file analysed.

STAGER has been developed and tested using more than 1 million epochs (an epoch is a 30-second sleep interval) in over 1,000 individuals. It is currently showing an overall accuracy of 80%. This exceeds the accuracy of our chosen predicate device and is comparable to human raters, who are the gold standard. We continue to evaluate STAGER against human raters and a predicate device to support substantial equivalence, which is a key to FDA clearance and market acceptance.

Level 4, 100 Albert Road, South Melbourne, Vic 3205
Email: info@medibio.com.au | www.medibio.com.au

A two-stage "evaluation" process was designed to optimize the STAGER algorithms. **Evaluation Stage 1** tested STAGER against three human raters. **Evaluation Stage 2** tested positive and negative percent agreement between STAGER and three expert human raters. In addition, we tested the algorithm performance consistency by processing signals from different sleep centers. Evaluation Stages 1 and 2 were performed using two sets of separate and distinct 40,000 sleep epochs.

The results of the Evaluation Stages 1 and 2 are illustrated in the following table:

	STAGER Average Agreement with the 3 Human Raters	**Average Agreement among the 3 Human Raters**
Wake	86%	88%
N1	36%	49%
N2	79%	80%
N3	92%	82%
REM	89%	82%
Overall	80%	79%

Additionally, STAGER has shown significantly faster processing time when compared to human raters, (seconds vs. hours). STAGER's overall agreement is comparable to expert human raters, who are considered the gold standard or best clinical practice for sleep medicine.

STAGER is now "locked" (i.e. no further changes can be made) and will enter the **"Validation phase"**. The validation phase will test up to 70 patients and is scheduled for completion by early in the June quarter of 2020.

Furthermore, if approved, STAGER will be the subject of an abstract entitled "***Better and faster automatic sleep staging with artificial intelligence: a clinical validation study of new software for sleep scoring"***. Pending conference acceptance of the submitted abstract, the STAGER study data will be unveiled at the SLEEP 2020 meeting (a joint venture of the American Academy of Sleep Medicine and the Sleep Research Society), which is scheduled to be held in Philadelphia, Pennsylvania June 13-17, 2020. Data will be presented by STAGER Principal Investigator Robert Hoch, M.D., Fellow of the American Academy of Sleep Medicine, Medical Director of Lakeland Health Services Sleep Center in Plymouth, Minnesota, and staff physician specialist in Sleep Medicine, Pulmonary Disease, and Critical Care Medicine with HealthPartners Medical Group in Minnesota.

It is important to note that the development of the STAGER is not expected to materially alter the projected timeframe for the De Novo submission for Depressive Burden (MEB-001).

ENDS

This announcement is authorized for release to the market by the Board of Directors of Medibio Limited.

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About Medibio Limited

Medibio (ASX: MEB) (OTCQB: MDBIF) is a mental 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 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.

Medibio Investor and Media Enquiries:
Peter Taylor
NWR Communications
peter@nwrcommunications.com.au
T: +61 (0) 412 036 231