ASX ANNOUNCEMENT

28 February 2024

Positive engagement with US FDA following Pre-submission meeting for MEB-001

Highlights:

- **Meeting provided TRI with a clear path to gain FDA clearance for MEB-001**
- **MEB-001 is TrivarX's innovative proprietary algorithm that assists in the diagnosis of current Major Depressive Episode (cMDE) using data obtained from in-clinic sleep studies**
- **Phase 2 Sleep Signal Analysis for Current Major Depressive Episode (SAMDE) study is progressing well, with 243 subjects enrolled to date**

Perth, Australia, and Minneapolis, USA: TrivarX Limited ('the **Company'**) (ASX: TRI) is pleased to provide the following update on the company's recent meeting with the United States (US) Food and Drug Administration (FDA) regarding the clearance of MEB-001.

MEB-001 is TrivarX's innovative, AI-backed algorithm to assist in the diagnosis of mood disorders in sleep study patients. MEB-001 uses AI and machine learning capabilities to extract and analyse biometric data, EEG (brain), ECG (heart rate), and heart rate variability signals attained from in-clinic sleep studies to screen and aid in the diagnosis of current Major Depressive Episode (cMDE).

TrivarX advises that the positive engagement with the FDA has defined a clear path toward gaining FDA clearance, and confirmed the De Novo pathway for MEB-001.

TrivarX will continue progressing with its comprehensive Phase 2 Sleep Signal Analysis for Current Major Depressive Episode (SAMDE) study, providing additional clinical data for regulatory submission.

To date, TrivarX has enrolled [243] subjects in the phase 2 study and remains on track to complete the initiative in the coming months. Upon completion of the trial, TrivarX will undertake further engagement with the US FDA regarding the requirements of any additional validation studies required before submission.

FDA clearance would unlock a significant market opportunity for the Company. It is estimated that 60 million people in the US suffer from poor sleep quality[1] and that 75% of people diagnosed with depression suffer from disrupted sleep patterns[2].

[1] Sleep Study | Johns Hopkins Medicine

[2] https://pubmed.ncbi.nlm.nih.gov/36644846/

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Management commentary:

Non-executive Chairman, David Trimboli said: *"The recent meeting with the US FDA was very encouraging and provides TrivarX with a clear path towards regulatory approval for MEB-001. The Company's Phase 2 SAMDE trial is progressing well and we look forward to utilising the latest data to further train and improve our innovative algorithm, prior to additional engagement with the regulator and a formal submission. Depression remains a major health concern in the USA and there is a distinct correlation between it and sleep disorders. We are confident that the broader commercialisation and potential uptake of MEB-001 will highlight this and assist the million of Americans currently suffering from debilitating mental health conditions like depression."*

This announcement is authorised for release by the Board of Directors of TrivarX Limited.

ENDS

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About TrivarX Limited:

TrivarX (ASX: TRI) (OTCPINK: 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 Perth (WA) and Minneapolis (MN, USA). TrivarX 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