ASX ANNOUNCEMENT

5 February 2024

Ongoing testing of proprietary algorithm delivers significantly increased performance metrics on Phase 2 SAMDE study data

Highlights:

- **In-depth analysis of Phase 1 results and data has further optimised TRI's proprietary algorithm, MEB-001, which aims to provide effective screening of current Major Depressive Episode (cMDE)**
- **This enhanced algorithm (trained only on Phase 1 data) was subsequently tested on 140 full-night and split-night polysomnography (PSG) tests from Phase 2 of the study**
- **Updated algorithm performance on Phase 2 data showed:**
  - **86% sensitivity and 75% specificity**
  - **44% positive predictive value and 95% negative predictive value**
- **Results provide considerable confidence in work undertaken to date and lay strong foundation for completion of Phase 2 SAMDE study**
- **Data analysis and algorithm optimisation work carried out to-date will inform TrivarX's in-person, pre-submission meeting with the US Food & Drug Administration (FDA) scheduled to occur in the coming weeks**
- **Phase 2 of the SAMDE study is progressing well – 220 of 400 participants enrolled to date with TRI on track for completion in coming months**

Perth, Australia, and Minneapolis, USA: TrivarX Limited ('the **Company'**) (ASX: TRI) is pleased to advise it has progressed a number of improvements to its proprietary algorithm (MEB-001), which is being developed as a screening and diagnostic aid for current Major Depressive Episode (cMDE).

The enhancements follow ongoing analysis utilising data and results from Phase 1 of TRI's comprehensive Sleep Signal Analysis for Current Major Depressive Episode (SAMDE) study, which was completed in July 2023 (refer ASX Announcement 24 July 2023). In addition to improvements in the sleep signal analysis algorithm, the team also identified two straight-forward patient-reported questions which when added to the sleep signal, were found to increase overall algorithm performance.

The process resulted in further refinement and optimisation of the algorithm, which was then applied to an initial sample of 140 subjects from the Company's ongoing Phase 2 trial (refer ASX announcement: 20 November 2023). The Phase 2 trial has been designed to further refine TRI's innovative AI-backed algorithm to detect cMDE for individuals who have been referred to a sleep clinic for polysomnography (PSG) tests.

Analysis of 140 subjects from the Phase 2 trial showed the proprietary algorithm reported an improvement across key performance parameters, comprising sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) (refer table below).

Measure	Description	TRI sample: 140 PSGs
Sensitivity	Ability for the test to correctly identify patients with the disease	**86%**
Specificity	Ability to designate an individual who does not have the disease as negative	**75%**
Positive Predictive Value	Likelihood that a person who has a positive test result does have the disease or condition	**44%**
Negative Predictive Value	Likelihood that an individual with a negative test result does not have the disease or condition	**95%**

The results generated to date provide the Company with confidence in its solution and ongoing clinical trial initiatives. Work will continue to further train and optimise the algorithm, but management anticipate that the enhanced solution will also provide a strong foundation for regulatory engagement with the US FDA.

The Phase 2 trial continues to progress well, with 220 participants recruited across multiple sleep centres in the US. TrivarX remains on track to complete Phase 2 during H1 CY2024.

Management commentary:

TrivarX Chief Medical officer, Archie Defillo, MD said: *"We are pleased to report the results from the latest round of optimisation testing for our proprietary algorithm to standardise the screening of cMDE.*

"These results provide considerable validation of the work undertaken during Phase 1, as well as our Phase 2 initiatives, Further, they clearly highlight the potential for our technology to provide a screening and diagnostic aid solution for cMDE that is safe and effective and meets the requirements for regulatory clearance and commercialisation.

"With the ongoing advancement of our Phase 2 trial, which has recently met the halfway mark in terms of patient recruitment, we are confident the results to-date significantly strengthen the Company's existing pathway to regulatory approval ahead of our FDA pre-submission meeting in the coming weeks."

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

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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.