ASX ANNOUNCEMENT

7 November 2024

Ground breaking advancement of depression screening tool significantly broadens patient reach and market opportunities

Newly developed algorithm achieves 87% sensitivity and 67% specificity in identifying current Major Depressive Episode (cMDE) using only a single lead ECG

Highlights:

- **Completion of R&D program culminates in the advancement of MEB-001 – designed for current Major Depressive Episode (cMDE) screening**
- **New algorithm uses only heart rate and heart rate variability as biomarkers to accurately conduct sleep staging and screen for cMDE**
- **Allows TrivarX to unlock large new addressable market opportunities outside of sleep centres including cardiology monitoring, sports and performance, military, treatment monitoring and consumer wearables**
- **Initial testing has provided promising results – new algorithm was tested on data from 295 phase 2 trial data subsets and delivered:**
    - **Sensitivity: 87% (95% CI 74-95%)**
    - **Specificity: 67% (95% CI 62-73%)**
- **Additional work underway to advance potential sponsored clinical trials utilising new algorithm, as well as testing and licensing opportunities**
- **Provisional patent application filed to strengthen competitive moat**

Perth, Australia, and Minneapolis, USA: TrivarX Limited ('the **Company'**) (ASX: TRI) is pleased to confirm the completion of an extensive R&D program which has culminated in the ground breaking advancement of its MEB-001 algorithm for the screening of current Major Depressive Episode (cMDE).

The new algorithm can accurately conduct sleep staging and screen for cMDE in subjects through a single channel ECG.

Currently, MEB-001, designed for use in sleep clinics using multiple sensors from a Type-1 polysomnography test which utilises multiple electrodes. The Company's innovative, new algorithm has been developed and optimised to use only a single channel ECG providing heart rate and heart rate variability metrics which can be used in sleep staging and cMDE screening.

Proof of concept testing has provided promising performance metrics, based on data from the Company's recently completed phase 2 Sleep Signal Analysis for Current Major Depressive Episode (SAMDE) study (refer ASX announcement: 30 July 2024).

This advancement expands the potential use case of MEB-001 into multiple hardware platforms and for use outside of sleep centres. Prospectively, it broadens application of the Company's technology into remote patient monitoring and licencing to wearable companies amongst other opportunities.

Performance:

The new algorithm was tested on an independent subset of 295 subjects, previously analysed by MEB-001 and referenced in the Company's phase 2 SAMDE study. In this assessment, the new algorithm showed:

Measure:	Description:	New algorithm performance	MEB-001 performance
Sensitivity	Ability for the test to correctly identify patients with the disease	**87% (95% CI 74-95%)**	**87% (95% CI 73-95%)**
Specificity	Ability to designate an individual who does not have the disease as negative	**67% (95% CI 62-73%)**	**72% (95% CI 66-77%)**

The results are encouraging, given the key performance parameters required to build a highly sensitive screening tool are high sensitivity and specificity.

The Company has filed a provisional patent application covering the new algorithm under 35 USC 111(b) with the US Patent and Trademark Office.

Next steps:

Given the promising performance metrics and large market opportunity unlocked by the new algorithm, the Company will continue to progress the opportunities associated with the new algorithm. TrivarX will continue to advance discussions with multiple industry participants around collaboration and potential licensing opportunities.

Management commentary:

Non-executive Chairman, David Trimboli said: *"The newly developed algorithm marks an important development in TrivarX's strategy of becoming the world leader in AI-based mental health assessments. Only requiring HR and HRV biomarkers will also serve to significantly increase the number of patients that the Company reaches and can unlock opportunities in remote patient monitoring, alongside specialist consumer devices and consumer wearables.*

"The new algorithm follows a targeted R&D program undertaken by the Company following the completion of its Phase 2 SAMDE study utilising MEB-001 and an ongoing review of TRI's extensive datasets. It has been shown to deliver very promising performance metrics, which will be further validated across data which will be generated from the Company's upcoming pivotal trial. This pivotal trial also has the potential to lead to FDA clearance for MEB-001, which will further strengthen the commercialisation opportunities and endorsement for both the Company's proprietary algorithms. We look forward to providing further updates on clinical and regulatory initiatives over the coming months."

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

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ASX ANNOUNCEMENT

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. 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