# ASX ANNOUNCEMENT

**8 October 2025**

## Positive interim results from US-veteran focused mental health trial

**Highlights:**

- **Interim results taken from ongoing clinical trial to screen for a current major depressive episode (cMDE) in veterans using single-lead technology**
- **Trial being undertaken with the Greater Los Angeles Research and Education Foundation (GLAVREF) and US Veterans Affairs (VA) Greater Los Angeles Healthcare System**
- **Interim results taken from 27 of first 30 patients and include:**
  - **Single-lead algorithm sensitivity: 94% (95% CI, 70-100%)**
  - **Single-lead algorithm specificity: 64% (95% CI, 31-89%)**
  - **MEB-001 sensitivity: 88% (95% CI, 62-99%)**
  - **MEB-001 specificity: 73% (95% CI, 39-94%)**
- **Results consistent with previous testing of 295 independent datasets from Phase 2 trial**
- **Work underway to finalise patient recruitment – 51 patients recruited to date**
- **Final analysis to be undertaken across 60 patient cohort in coming weeks**

**Perth, Australia, and Minneapolis, USA: TrivarX Limited** ('the **Company'**) (ASX: TRI) is pleased to provide positive interim results from the Company's clinical trial alongside the Greater Los Angeles Research and Education Foundation (GLAVREF) and US Veterans Affairs (VA) Greater Los Angeles Healthcare System evaluating its novel single-lead ECG algorithm to screen for current major depressive episodes (cMDE) in veterans with suspected sleep apnoea (refer ASX Announcement 28 April 2025).

The single-channel ECG algorithm utilised in the trial is an extension of TrivarX's lead asset, MEB-001. The algorithm accurately performs sleep staging and detects cMDE in subjects using only heart rate (HR) and heart rate variability (HRV) metrics.

**Positive results highlight considerable algorithm potential in veterans:**

The objective of this trial is to assess the sleep scoring accuracy of TrivarX's single-channel ECG algorithm, comparing it to gold standard human-rated polysomnography (PSG), and evaluate the algorithm's cMDE determination against the clinical gold standard of using the Mini International Neuropsychiatric Interview (MINI) administrated by a health professional.

Interim analysis was taken 27 of the 30 participants enrolled through the VA Greater Los Angeles Healthcare System. Three participants were not included in the analysis due to insufficient data capture.

Of the subject sample, the prevalence of cMDE was 63.3%. Both the Company's MEB-001 and single-channel algorithms demonstrated strong sensitivity compared to clinician diagnosis of 88% (95% CI, 62-99%) and 94% (95% CI, 70-100%) respectively, with specificities of 73% (95% CI, 39-94%) and 64% (95% CI, 31-89%).

Interim analysis highlighted similar performance between MEB-001 and the single-lead algorithm, underpinning additional validation for the Company's innovative single-lead offering. Interim analysis results are also consistent with previous testing across 295 independent data subsets from the Company's phase 2 trial (refer ASX announcement: 7 November 2024).

Analysis from phase 2 data showed single-lead algorithm sensitivity of 87% (95% CI 74-95%), compared to MEB-001 which delivered 87% (95% CI 73-95%) and specificity of 67% (95% CI 62-73%) from the single-lead and 72% (95% CI 66-77%) from MEB-001. A summary of the Phase 2 trial analysis and recently completed interim analysis is as follows:

| Measure: | Single-lead (Phase 2 data) | MEB-001 (Phase 2 data) | Single lead (VA trial ) | MEB-001 (VA trial) |
|---|---|---|---|---|
| **Sensitivity** | **87% (95% CI 74-95%)** | **87% (95% CI 73-95%)** | **94% (95% CI, 70-100%)** | **88% (95% CI, 62-99%)** |
| **Specificity** | **67% (95% CI 62-73%)** | **72% (95% CI 66-77%)** | **64% (95% CI, 31-89%)** | **73% (95% CI, 39-94%)** |

**Next steps:**

TrivarX will now focus on completion of patient recruitment to finalise the trial. Currently, a total of 51 patients have been enrolled. Once enrolment is completed, the Company will undertake a full results analysis from the 60 participants.

Concurrently, the Company is assessing a range of commercial opportunities to extract value from both MEB-001 and its single-lead algorithm technology offerings.

**Management commentary:**

**Principal Investigator, Dr Jennifer Martin said:** *"The study is progressing well with promising preliminary findings regarding the sensitivity and specificity for identifying current major depression as compared to gold-standard clinical assessments."*

**Non-executive Chairman, David Trimboli said:** *"These interim results represent an important step forward in our collaboration with the VA Greater Los Angeles Healthcare System and GLAVREF. Demonstrating strong sensitivity in detecting major depressive episodes, the data reinforces the potential clinical utility of both MEB-001 and our single-lead algorithm. Further, we are encouraged with their consistency across historical studies, which include larger datasets."*

*"We now remain focused on completing patient recruitment, alongside our respected clinical trial partner in the VA, while also advancing commercial opportunities to unlock the value of our technology. We look forward to delivering on additional operational milestones in the coming weeks."*

**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. 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