

20 June 2024

## 362 patients enrolled in Phase 2 Sleep Signal Analysis for Major Depressive Episode (SAMDE) study

### Highlights:

- Major patient enrolment update in TRI's phase 2 Sleep Signal Analysis for Current Major Depressive Episode (SAMDE) study utilising MEB-001 with 362 of 400 patients recruited
- MEB-001 is TrivarX's proprietary algorithm which utilises artificial intelligence (AI) to assist with the effective screening of a current Major Depressive Episode (cMDE)
- TRI expects completion of phase 2 study and results to materialise in the coming weeks
- Results of phase 2 SAMDE study to inform ongoing engagement with United States (US) Food and Drug Administration (FDA) approval for MEB-001
- Strategic advisor, W Drew Palin, M.D. appointed to advance commercial opportunities commencing in July 2024
- Mr Palin is a seasoned healthcare executive with over 30 years' experience
- Company recently participated at SLEEP 2024 to showcase its technology – providing management with the opportunity to promote its solutions to industry participants

**Perth, Australia, and Minneapolis, USA:** TrivarX Limited ('the Company') (ASX: TRI) is pleased to provide a major patient enrolment update in its Phase 2 Sleep Signal Analysis for Current Major Depressive Episode (SAMDE) study utilising its proprietary AI-backed algorithm, MEB-001. The Company has also appointed a US-based strategic advisor to assist with advancing commercial opportunities associated with TrivarX's innovative product suite.

### Patient recruitment update:

The Company advises it has recruited 362 of the proposed 400 patients for its Phase 2 SAMDE study, which aims to continue to validate TRI's MEB-001 algorithm (MEB-001) to assist in the screening and diagnosis of a current major depressive episode (cMDE) in test subjects.

The Company expects to complete the trial in the coming weeks and report results shortly thereafter. TrivarX is confident that any positive data from the study will provide further regulatory validation for its proprietary algorithm prior to further engagement with the US Food and Drug Administration (FDA).

### Appointment of seasoned healthcare executive as strategic advisor:

TrivarX has also appointed W. Drew Palin M.D. as a strategic advisor to advance a number of corporate opportunities. Mr Palin is a seasoned healthcare executive and an innovative entrepreneur with over 30 years of experience in the medical technology sector.

Mr Palin is currently Chief Business Officer of American Gene Technologies. He has held a number of senior positions in the US healthcare sector, including Medical Innovation Officer at Preventice (acquired by Boston Scientific for ~USD\$925m+) and Chief Development Officer at leading insurance provider Blue Cross of Northeastern Pennsylvania. Mr Palin is also a seasoned entrepreneur, founding

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AI-patient access company Intellivisit Solutions and claims-based health software business ThinkMED. These roles have provided him with extensive experience in medical technology commercialisation.

As part of his role, Mr Palin will assist the Company in advancing a number of commercial opportunities including additional partnership agreements, licencing opportunities and commercialisation initiatives.

### **Participation at SLEEP 2024:**

TrivarX also recently participated in SLEEP 2024, which is an annual meeting of the Associated Professional Sleep Societies, which is a joint venture between the American Academy of Sleep Medicine and the Sleep Research Society.

The event was held in Houston, Texas between 1 June and 5 June and provided the Company with a number of opportunities to present its technology to researchers, device companies, distributors and other industry participants. The Company advises that this has led to a number of follow up engagements.

### **Management commentary:**

**Non-executive Chairman, David Trimboli said:** *"The successful patient enrolment to date for TrivarX's comprehensive Phase 2 SAMDE study is a testament to the hard work of our clinical field team and research partners – all of whom have consistently operated at a high level to bring a trial of this scale towards completion. We remain fully committed to our development pathway for the MEB-001 algorithm – a clinically-backed AI solution that aims to provide more effective screening of a current Major Depressive Episode (cMDE) and achieve improved patient health outcomes."*

*"Heading into the second half of the 2024 calendar year, the Company looks forward to providing key updates as the results of the Phase 2 study are received, which will in turn support ongoing dialogue with the US FDA where the Company has already established a clear route to regulatory approval for MEB-001 through the De Novo pathway."*

*"As the Company continues to build momentum with its clinical development pathway, I am also pleased to welcome Mr W Drew Palin, M.D. as a strategic advisor to the business. As a veteran medtech entrepreneur in the US market, Mr Palin's skills and experience will complement the existing skills of the TrivarX board and management team as the Company moves towards commercialisation."*

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

**ENDS**

### **Investor Enquiries:**

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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](http://www.otcmarkets.com) and [www.asx.com.au](http://www.asx.com.au)