ASX ANNOUNCEMENT

28 November 2024

Chairman's update

Annual General Meeting of TrivarX Limited held on Thursday, 28 November 2024 at 9:00am (AWST)

Dear fellow Shareholders,

It is my pleasure to present this report for the 2024 Annual General Meeting of TrivarX Limited ('**TrivarX'** or 'the **Company'**) (ASX: TRI).

This time last year, the Company was focused on executing a number of key deliverables which had been set out by new Directors to the Company, including myself. This strategy was very clear and centred on advancing the development of innovative, AI-backed solutions for mental health screening.

The rationale for pursuing mental health screening stemmed from the epidemic being felt in the US and more broadly. A large portion of the population suffer from mental health conditions and they are commonly underdiagnosed, misdiagnosed and not tested for.

Existing mental health screening protocols are also primarily subjective, which provides an exceptional opportunity for TrivarX in its pursuit of commercialising technology which can be implemented into or used alongside existing measures, like a sleep study or commonly used wearable devices to provide clinicians and patients with the data required to reduce the overbearing burden of conditions.

Corporate deliverables achieved in the last 12 months included a broad Board and management transition which has attracted a number of industry professionals with very accomplished track records, consolidation the Company's capital structure, executing a change of company name and attracting new funding to provide balance sheet strength for the completion of the company's Phase 2 Sleep Signal Analysis of Depression Burden (SAMDE) study for our innovative lead asset, MEB-001.

Following the execution of these initiatives which predominately came to fruition in H2 CY23, TrivarX was left well positioned to rapidly advance its stated strategy to drive growth through ongoing clinical trial and R&D developments.

With a strong framework for growth, operations during the period were highlighted by the completion of the Company's Phase 2 SAMDE trial. This trial followed a very promising Phase 1 and was deemed crucial to gain the required data to progress multiple workstreams which are now coming into fruition.

Patient recruitment for Phase 2 commenced in November CY23, following onboarding of 15 leading sleep centres across the US. Total sites were upsized following considerable demand from industry participants, based on Phase 1 trial results and the innovative nature of MEB-001 in an industry which is ripe for disruption.

The trial subsequently commenced towards the second half of CY23 and throughout the course of H1 CY24 enrolled and tested 400 patients, with a primary aim to validate MEB-001's ability in screening for current Major Depressive Episode (cMDE) in test subjects.

Upon completion of the trial, the Company attained one of the world's largest databases of sleep polysomnography data, labelled with clinical level mental health assessments, which is a major competitive advantage.

Results from the trial were deemed exceptionally positive and highlighted MEB-001's distinct ability to detect the likelihood of cMDE in trial participants. Specifically, performance parameters showed sensitivity of 87% (95% CI 73-96%) and specificity of 72% (95% CI 66-77%).

Pleasingly, this highlighted a material increase in sensitivity from 71% in Phase 1 to 87% in Phase 2, noting the algorithm's ability to correctly identify participants with depression. Collectively, the performance parameters placed MEB-001 into the upper end of existing depression screening tools and laid a very strong foundation for the Company's regulatory approval opportunities and future product sales.

Data from the trial has unlocked a number of additional workstreams for TrivarX, including ongoing liaison with the US Food and Drug Administration (FDA) to define a regulatory pathway for MEB-001, which will provide exceptional validation of our offering in the world's largest medical market.

Following ongoing engagement with the regulator, the Company will pursue the De Novo clearance pathway, with our final clinical requirement set to commence early next year via a pivotal study. The design for this pivotal study is anticipated to be approved at a meeting with the FDA on 17 December 2024, with a final dossier expected to be lodged mid-CY25.

Further to this, work associated with ongoing algorithm development has presented considerably larger market opportunities.

Most recently, our highly skilled development team has developed a groundbreaking depression screening tool that only uses a single channel ECG. The new product cites heart rate and heart rate variability as biomarkers to conduct sleep staging and screen for cMDE. This was validated via proof-of-concept results, which showed high levels of sensitivity and specificity.

This marked a very important transition for the Company and unlocked a much clearer pathway to deploy our technology in home settings and outside of sleep centres, through commonly available and widely used wearable devices. This significantly increases the size of our market opportunity through broader reach and potential for additional use cases.

Work to expand the potential use cases for MEB-001 and the Company's associated algorithms is now underway. These will explore the use of TrivarX's technology in multiple hardware platforms and common wearable devices via our own work, as well as through potential clinical trials with large hospital groups which will provide a better understanding of its potential across various cross sections of the population in the US and internationally.

Looking back, the 2024 financial year marked a key period of transition for the business that required strong execution from the Board and management team. We are pleased to have met our objectives in that regard, setting the Company up for an exciting period ahead in our clinical development pathway.

Over the coming quarters, the Company will remain focused on executing its pivotal trial, as well as advancing new opportunities presented to us in connection with the successful development on our single-channel ECG product.

As this is our AGM, I would like to take this opportunity to thanks shareholders for their ongoing support through our journey. TrivarX has achieved an incredible amount over the last 12 months, and we look forward to updating investors on each of our near-term value accretive milestones that are now in sight.

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