

30 April 2025

Quarterly Activities Report: Landmark mental health clinical trial with US government agency underpins strong progress

Highlights:

- **TrivarX, the Greater Los Angeles Research and Education Foundation (GLAVREF) and the US Department of Veterans Affairs (VA) to undertake clinical trial to screen for a current major depressive episode (cMDE) using TRI's technology**
- **Trial protocol submitted to the VA's Institutional Review Board (IRB) and approved post period end – Site selection and patient recruitment to commence imminently**
- **Trial to recruit 60 patients across multiple sites and take 12 weeks from commencement**
- **Trial to use TRI's innovative single-channel mental health screening algorithm**
- **TRI's groundbreaking technology uses only heart rate and heart rate variability to accurately conduct sleep staging and screen for cMDE**
- **Trial and other pending R&D anticipated to unlock commercialisation opportunities for expanded use of innovative technology**
- **Pre-submission meeting with US FDA held to finalise pivotal study design for MEB-001 – trial marks the final clinical requirement prior to approval**
- **Firm commitments to raise \$2.25m secured resulting in cash at bank of \$1.5m at quarter end with \$707,000 to be received in the coming weeks**

Perth, Australia, and Minneapolis, USA: TrivarX Limited ('the Company') (ASX: TRI) is pleased to provide the following report on activities for the three-month period ended 31 March 2025 (the "quarter").

During the quarter, TrivarX worked alongside the US Department of Veterans Affairs ('VA') and the Greater Los Angeles Veterans Research and Education Foundation ('GLAVREF') to submit a trial protocol to undertake an innovative mental health clinical trial. The Company also strengthened its balance sheet via a strategic capital raise, and made several key advancements with respect to the regulatory approval pathway for MEB-001.

Innovative mental health clinical trial alongside the US Department of Veterans Affairs:

TrivarX worked closely with the VA and GLAVREF to submit a trial protocol to the VA's Institutional Review Board ('IRB'), which was approved post quarter end (refer ASX announcement 28 April 2025). As part of this, TrivarX also entered into a Cooperative Research and Development Agreement ('CRADA') with these groups to formalise the relationship.

The US Department of Veterans Affairs is a cabinet level executive branch department of the federal government charged with providing lifelong healthcare services to eligible military veterans via 170 VA medical centres and outpatient clinics located throughout the US. GLAVREF is a US-based not-for-profit organization that supports VA approved research.

This will result in the Company alongside the VA, undertaking a clinical trial to assess the sleep scoring accuracy of TrivarX's single-channel ECG algorithm comparing it to gold standard human-rated polysomnography, and will evaluate the algorithm's current Major Depressive Episode (cMDE) determination against the clinical gold standard of using the Mini International Neuropsychometric

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Interview (MINI) administered by a health professional. In addition to using the single-lead ECG signal, patients will also wear a wrist-worn wearable device during the night providing the company with additional data for further R&D and commercialisation.

A total of 60 trial participants with suspected sleep apnoea will be sourced from multiple sites including the VA's network in the US. The trial is expected to take approximately 12 weeks from commencement.

TrivarX's single-channel algorithm is an extension of lead asset, MEB-001. The algorithm accurately conducts sleep staging and screens for cMDE in subjects using heart rate (HR) and heart rate variability (HRV) metrics alone. Results from the Company's Phase 2 trial on 195 patients demonstrated a sensitivity of 87% (95% CI 74-95%) and specificity of 67% (95% CI 62-73%). Site selection and patient recruitment initiatives are now underway.

Pre-submission meeting with the US FDA for pivotal trial design:

The Company undertook a pre-submission meeting with the United States (US) Food and Drug Administration (FDA) regarding its pivotal study design and clearance route for MEB-001, which provided clear validation of TrivarX's proposed study design for the proposed pivotal trial.

MEB-001 is TrivarX's innovative, AI-backed algorithm that assists with screening of mental health conditions in sleep study patients. MEB-001 uses AI and machine learning capabilities to extract and analyse biometric data, EEG (brain), ECG (heart rate), and heart rate variability signals attained from in-clinic sleep studies to screen and aid in the diagnosis of current Major Depressive Episode (cMDE). In the Company's 400 patient Phase 2 trial, MEB-001 achieved a sensitivity of 87% and specificity of 72% (refer ASX announcement: 30 July 2024).

This trial is the final requirement before TrivarX can submit MEB-001 for FDA approval via the De Novo pathway. The Company continues to advance discussions with US sleep centres and hospitals to determine study sites.

Management commentary:

Non-executive Chairman, David Trimboli said: *"The work carried out in the March quarter has positioned the Company to advance to the next phase of our clinical development pathway for MEB-001, alongside best-in-class partners and in accordance with our own high standards for trial design and regulatory engagement. Our work during the quarter presents TrivarX with a unique opportunity to pursue clinical validation alongside a major US institution which shares our commitment to achieving an improved standard of care for mental health."*

"The potential opportunity now in front of the Company was reflected by the strong support we received in our strategic capital raise, which positions TrivarX with extra capital flexibility to advance our comprehensive trial with the VA and GLAVREF. We look forward to providing more near-term updates in the June quarter as the trial progresses."

Corporate:

Placement to raise \$2.25m:

TrivarX secured firm commitments from a range of institutional, sophisticated and professional investors to raise \$2.25 million through the issue of 150,000,000 new fully paid ordinary shares ("Shares") at an issue price of \$0.015 per share (the "Placement").

The Placement is being conducted in two tranches. The first tranche of 102,818,898 Shares issued under the Placement were issued pursuant to the Company's placement capacity under ASX Listing Rules 7.1 and 7.1A. (Tranche 1 Placement Shares), representing approximately 22% of the shares on issue at that time. The second tranche, being subject to shareholder approval at the General Meeting

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(**Meeting**) to be held on 13 May, is to issue circa 47.18 million fully paid ordinary shares (Tranche 2 Placement Shares). Also subject to shareholder approval at the Meeting, participants in the Placement will be issued one free attaching option for every two new Shares issued with an exercise price of \$0.025 and expiring 2.5 years from the date of issue.

The Company anticipates settlement of the second tranche in within a fortnight after the Meeting, which will provide an additional \$707,700 in new funding.

Financial overview:

Cash at bank as at 31 March 2025 was \$1.56m, with an additional \$707,700 expected to be received from settlement of the second tranche. As per item 6 of the attached Appendix 4C cash flow report for the quarter, \$15,000 was paid in director fees. There were no other payments to related parties and their associates of TrivarX Limited.

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

ENDS

Investor Enquiries:

Henry Jordan – Six Degrees Investor Relations
Henry.jordan@sdir.com.au
+61 431 271 538

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. 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.otcm Markets.com and www.asx.com.au

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

TRIVARX LIMITED

ABN

58 008 130 336

Quarter ended ("current quarter")

31 MARCH 2025

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	-	-
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	-	-
(f) administration and corporate costs	(330)	(1,047)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	1	6
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives (2024 R&D Tax Incentive)	-	1,031
1.8 Other (GST Refund)	-	49
1.9 Net cash from / (used in) operating activities	(329)	39
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	(342)	(1,416)
(f) other non-current assets	-	-
2.2 Proceeds from disposal of:		
(a) entities	-	-
(b) businesses	-	-

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	(342)	(1,416)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	1,563	2,289
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(107)	(155)
3.5	Proceeds from borrowings		500
3.6	Repayment of borrowings	-	(500)
3.7	Transaction costs related to loans and borrowings	-	(28)
3.8	Dividends paid	-	-
3.9	Other (payment of lease liabilities)	(25)	(72)
3.10	Net cash from / (used in) financing activities	1,431	2,034

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	809	848
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(329)	39
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(342)	(1,416)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,431	2,034
4.5	Effect of movement in exchange rates on cash held	(3)	61
4.6	Cash and cash equivalents at end of period	1,566	1,566

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	1,566	809
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	1,566	809

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	15
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.</i>		

7.	Financing facilities <i>Note: the term 'facility' includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	Total financing facilities	-	-
7.5	Unused financing facilities available at quarter end		-
7.6	Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		
	N/A		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(329)
8.2	Cash and cash equivalents at quarter end (item 4.6)	1,566
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	1,566
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1) <i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	4.8
8.6	If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1	Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
	N/A	
8.6.2	Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
	N/A	
8.6.3	Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
	N/A	
	<i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>	

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 30 April 2025

Authorised by: By the Board
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.