

31 January 2025

Quarterly Activities Report: MEB-001 regulatory pathway advanced alongside ongoing algorithm development to expand total addressable market

Highlights:

- Extensive work undertaken to finalise planned pivotal trial design prior to meeting with FDA
- Meeting established confidence on clinical trial design for planned pivotal trial of MEB-001 prior to formal regulatory submission
- MEB-001 is TRI's innovative proprietary algorithm that assists in screening of current Major Depressive Episode (cMDE) using data obtained from in-clinic sleep studies
- Algorithm has been validated in a Phase 2 trial for cMDE and delivered promising algorithm performance metrics
- Negotiations with prominent hospitals and sleep centres for pivotal trial continued, with collaborations anticipated to provide access to high volume sites
- Completion of focused R&D program led to advancement of MEB-001 algorithm and introduction of new algorithm which broadens patient reach and market opportunities
- New algorithm uses only heart rate and heart rate variability as biomarkers to accurately conduct sleep staging and screen for cMDE
- 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%)
- Work to advance new algorithm continued and included discussions with potential partners for additional validation testing and licensing
- New algorithm unlocks large new addressable market opportunities outside of sleep centres including cardiac and treatment monitoring, military and wearables

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 December 2024 (the "quarter").

During the quarter, the company advanced work towards its pre-submission with the United States (US) Food and Drug Administration (FDA) regarding its pivotal study design and clearance route for MEB-001, and also developed and optimised a new algorithm which has the potential to considerably broaden the Company's total addressable market, solution applications and potential use cases.

CLINICAL BUSINESS UNIT:

Work towards pre-submission meeting with the US FDA for upcoming pivotal trial:

The Company advanced work associated with its pivotal study design and clearance route for MEB-001, ahead of a pre-submission meeting with the FDA (see ASX announcement 28 January 2025).



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).

Throughout the period, the Company finalised the plans for the proposed pivotal trial, which were subsequently presented to the FDA. During this meeting, clear validation of the proposed study design was provided.

The trial will utilise an adaptive design allowing for interim data analysis. TrivarX plans to recruit a minimum of 563 patients from at least five US study sites. Primary inclusion criteria will be patients between 22 years and 75 years of age who have been referred to a sleep clinic for sleep disturbances.

During the trial, MEB-001 will be compared to the clinically-administered fully structured MINI Module A (incorporating Module O by reference) which was confirmed in the pre-submission meeting as a gold standard cMDE diagnosis.

This trial is the final clinical requirement prior to TrivarX submitting MEB-001 for FDA approval via the De Novo pathway.

Negotiations with several prominent US sleep centres and hospitals to determine key study sites was ongoing. Partnership engagement is well advanced and is anticipated to unlock a number of high-volume locations for the trial.

NON-CLINICAL BUSINESS UNIT:

Groundbreaking depression screening tool to expand total addressable market:

TrivarX confirmed the completion of an extensive R&D program, which culminated in the innovative advancement of MEB-001 for the screening of cMDE. The new algorithm developed from the program can accurately conduct sleep staging and screen for cMDE in subjects via single channel ECG.

At present, MEB-001 is designed for use in sleep clinics and uses multiple sensors from a Type-1 polysomnography test which requires multiple electrodes. The new algorithm has been developed and optimised to use only a single channel ECG which provides heart rate and heart rate variability metrics. These can be confidently used in sleep staging and cMDE screening.

Initial proof of concept testing was undertaken during the quarter using TRI’s Phase 2 Sleep Signal Analysis for Current Major Depressive Episode (SAMDE) study (refer ASX announcement: 30 July 2024).

During this testing, the new algorithm was tested on an independent subset of 195 patients and 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%)

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

The advancement and initial testing considerably expands the potential use case for MEB-001 and the Company's new algorithm into multiple hardware platforms and for use outside of sleep centres.

The Company is currently assessing a number of remote patient monitoring opportunities, as well as licensing opportunities with large wearable technology companies.

To fast-track ongoing development and proof of concept testing, the Company is in well advanced discussions with potential partners and research groups to undertake additional testing.

Management commentary:

Non-executive Chairman, David Trimboli said: *"The Company has made considerable progress during the quarter, in line with its stated strategy for the clearance and commercialisation of MEB-001 and associated algorithms."*

"Pleasingly, work associated with the planned pivotal trial advanced well and TrivarX has now established confidence in the trial design. We have also been encouraged by engagement from industry groups who have expressed interest in providing sites for the trial. These discussions have progressed well over recent months and will provide the Company with extensive access to a large patient population."

"Further, the development of the Company's new algorithm provides an exceptional opportunity to broaden patient reach and enter new markets. Building a tool that only requires HR and HRV biomarkers marks a very important development in our commercialisation journey and stated strategy in becoming the world leader in AI-based mental health assessments."

Corporate and financial overview:

R&D loan facility repaid:

TrivarX entered into a short-term loan facility agreement with Kashcade RD1 Pty Ltd (Lender) for the amount of \$500,000 (Loan) (see ASX announcement 1 October 2024) The R&D loan facility was established against the anticipated R&D tax rebate for the FY24 period and used for working capital purposes.

The Loan, which had an establishment fee of 2% and bore interest of 1.38% per month was repaid in December 2024 following receipt of the R&D tax incentive.

\$1.03m R&D tax rebate secured:

The Company confirmed receipt of \$1,031,073 for its Research & Development (R&D) Tax Incentive for FY23-24 (see ASX announcement 6 December 2024). The incentive relates to TrivarX's eligible expenditure in connection with its Phase 2 SAMDE study, work towards the pending pivotal study and the ongoing development and commercialisation of its sleep staging software.

The Australian federal government's R&D Tax Incentive is an important program that encourages companies to engage in research and development benefitting Australia by providing a tax offset. Based on TrivarX's turnover, the tax offset was 43.5% of the expenditure on eligible activities.

ASX ANNOUNCEMENT



Financial overview:

Cash at bank as at 31 December was \$809,000 compared to \$1.121 million at 30 September. As per item 6 of the attached Appendix 4C cash flow report for the quarter, \$14,000 was paid to directors for 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

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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. Through their Corporate Health product, the Company offers mental well-being solutions for businesses and are also developing products to serve the healthcare provider market. 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.otcm Markets.com and www.asx.com.au

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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 DECEMBER 2024

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 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	(336)	(717)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	2	5
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	1,031
1.8 Other (provide details if material)	49	49
1.9 Net cash from / (used in) operating activities	746	368

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	(545)	(1,074)
(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	(545)	(1,074)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	726
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	-	(48)
3.5	Proceeds from borrowings		500
3.6	Repayment of borrowings	(500)	(500)
3.7	Transaction costs related to loans and borrowings	(18)	(28)
3.8	Dividends paid	-	-
3.9	Other (payment of lease liabilities)	(19)	(47)
3.10	Net cash from / (used in) financing activities	(537)	603

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	1,121	848
4.2	Net cash from / (used in) operating activities (item 1.9 above)	746	368
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(545)	(1,074)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(537)	603
4.5	Effect of movement in exchange rates on cash held	24	64
4.6	Cash and cash equivalents at end of period	809	809

Appendix 4C

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

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	809	1,121
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)	809	1,121

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	14
6.2	Aggregate amount of payments to related parties and their associates included in item 2	14
<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)	746
8.2	Cash and cash equivalents at quarter end (item 4.6)	809
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	809
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	N/A
<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>		
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: 31 January 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.