ASX ANNOUNCEMENT

30 October 2024

Quarterly Activities Report: Promising performance results from Phase 2 SAMDE study underpin ongoing regulatory engagement

Highlights:

- **Positive results from Phase 2 Sleep Signal Analysis for Current Major Depressive Episode (SAMDE) study, with MEB-001 achieving a sensitivity of 87% and specificity of 72%**
- **Results of Phase 2 study to inform ongoing engagement with United States (US) Food and Drug Administration (FDA) and De Novo clearance for MEB-001 with a pre-submission meeting with FDA scheduled for this quarter to finalise pivotal study design**
- **Planned pivotal trial is the final step before submitting to the FDA under the De Novo pathway**
- **Significant healthcare experience added to the board with appointments of Dr Tony Keating as Executive Director and Mr John H Mathias II as Non-Executive Director**

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 30 September 2024 (the "quarter").

During the quarter, the Company completed a significant milestone in its Phase 2 Sleep Signal Analysis for Current Major Depressive Episode (SAMDE) study, which utilises TrivarX's proprietary AI-driven algorithm, MEB-001. Results from the study further validate MEB-001's potential to assist in the screening for a current Major Depressive Episode (cMDE) in test subjects. The Company also considerably strengthened its Board with the appointment of two experienced healthcare executives, while advancing regulatory discussions with the US FDA to finalise a pivotal clinical trial protocol, expected to commence in the coming months.

Operational overview:

CLINICAL BUSINESS UNIT:

Completion and results of Phase 2 SAMDE study:

During the period, the Company achieved a major milestone in the completion of its Phase 2 SAMDE study and reported promising results. The objective of the study (ClinicalTrials.gov ID NCT05708222) was to use MEB-001 to detect the likelihood of a cMDE using Clinician Reporting Outcomes (CRO) assessment in individuals referred to sleep clinics.

During the trial, a total of 400 patients were recruited via 15 sleep centres in the US. Of these, 73 patients were excluded due to incomplete data or a split night/titration sleep study. MEB-001 also automatically identified 32 patients with significant anomalies in their sleep data. The MEB-001 algorithm was locked prior to the analysis ensuring no data from Phase 2 was used in its training.

Analysis of the results showed MEB-001's strong performance, with a sensitivity of 87% (95% CI 73-96%) and specificity of 72% (95% CI 66-77%). These results represent a significant improvement in sensitivity, up from 71% in the Phase 1 trial to 87%. The Phase 2 study results confirmed MEB-001's ability to accurately identify individuals with cMDE, further validating its potential as a diagnostic tool.

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

Following receipt and analysis of the Phase 2 results, the Company submitted a formal request to the US Food & Drug Administration (FDA) for a pre-submission meeting to finalise the pivotal trial design for MEB-001.

This pivotal trial is the final requirement before TrivarX can submit MEB-001 for FDA approval via the De Novo pathway. The meeting with the FDA is expected to occur this quarter. Upon completion, the Company expects to be in a position to commence the pivotal trial, with an FDA submission to follow in H1 CY2025.

In the lead up to the pivotal trial, a number of prominent and high-profile US sleep centres and research organisations have expressed interest in collaborating. These partnerships will help fast-track the trial's completion at high-volume sites.

NON-CLINICAL BUSINESS UNIT:

Appointment of Dr Keating as Executive Director:

TrivarX strengthened its leadership team with the appointment of Dr Tony Keating, effective 29 July 2024. Dr Keating brings a wealth of executive experience in the healthcare industry, where he has successfully combined strong technical expertise with a demonstrated track record in bringing innovative health solutions through to commercialisation.

Prior to his appointment to the Board of TrivarX, Dr Keating co-founded and served as CEO of ResApp Health, a digital health company which successfully developed groundbreaking smartphone technology for accurately diagnosing respiratory diseases through cough analysis.

He led ResApp through successful R&D phases, global regulatory approvals and commercial partnerships, culminating in the sale of the company to Pfizer in 2022 for $180m.

Appointment of John H. Mathias II as a Non-Executive Director:

The Company further strengthened its Board with the appointment of Mr John H. Mathias II, effective 1 October 2024. Mr Mathias is an accomplished healthcare focused operations and business development executive with a 30-year career in the US healthcare sector.

He currently serves as Chief Development Officer at Medbridge Healthcare, one of the largest sleep disorder diagnostic outsourced service providers in the US which performs over 80,000 sleep diagnostic procedures annually. Previously, he was Chief Operating Officer and President of Sleep Services of America Inc., an entity of Johns Hopkins Health System, where he managed operations for sleep diagnostics and therapeutic coordination, oversaw strategic M&A and led a business turnaround which returned the division to profitability.

Management commentary:

Non-executive Chairman, David Trimboli said: "*Our operational milestones during the quarter, highlighted by the completion of the comprehensive Phase 2 SAMDE Study, marked the culmination of significant period of research in our clinical development pathway for MEB-001.*

"In particular, the strong results from the Phase 2 study have further reinforced our view that AI technology can be used to achieve improved health outcomes for effective depression screening compared to the current standard of care.

"As our clinical program advances, the Phase 2 results have established a sound framework for the design of our pivotal trial, which will in turn underpin our formal FDA submission under the De Novo

pathway for novel treatments. It was also my pleasure during the quarter to welcome Dr Tony Keating and Mr John Mathias to the Board in their respective roles. As TrivarX moves towards commercialisation, both Tony and John's skill-sets and backgrounds are ideally suited to help oversee the Company's next phase of development."

Corporate and financial overview:

R&D loan facility secured:

TrivarX entered into a short-term loan facility agreement with Kashcade RD1 Pty Ltd (Lender) for the amount of $500,000 (Loan). The R&D loan facility has been established against the Company's anticipated R&D tax rebate for the FY24 period and will be used for working capital purposes.

The Loan has an establishment fee of 2% and bears interest of 1.38% per month with an initial maturity date of 30 November 2024 which can be extended for an additional 30 days upon agreement by the Lender.

Financial overview:

Cash at bank as at 30 September 2024 was $1.12m following receipt of $500,000 from the R & D loan facility with Kashcade RD1 Pty Ltd (as described above) and $726k from the second tranche of the Placement announced on 2 May 2024.

During the quarter, the Company spent $378,000 on operating activities compared to $273,000 for the June quarter. This increase was mainly due to timing of the fees for outsourced accounting services in the U.S. and other costs associated with the Placement and financing arrangements.

As per item 6 of the attached Appendix 4C cash flow report for the quarter, only $8k was paid to Tony Keating 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.otcmarkets.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	**Quarter ended ("current quarter")**
58 008 130 336	30 SEPTEMBER 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 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	(381)	(381)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	3	3
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(378)**	**(378)**

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	(529)	(529)
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(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**	**(529)**	**(529)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	726	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)	(48)
3.5	Proceeds from borrowings	500	500
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	(10)	(10)
3.8	Dividends paid	-	-
3.9	Other (payment of lease liabilities)	(28)	(28)
3.10	**Net cash from / (used in) financing activities**	**1,140**	**1,140**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	848	848
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(378)	(378)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(529)	(529)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,140	1,140
4.5	Effect of movement in exchange rates on cash held	40	40
4.6	**Cash and cash equivalents at end of period**	**1,121**	**1,121**

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	1,121	848
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)**	**1,121**	**848**

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	8
6.2	Aggregate amount of payments to related parties and their associates included in item 2	8

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.

7.	**Financing facilities** *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.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	500	500
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	500	500

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.	

7.1: Short term loan facility with Kashcade RD1 Pty Ltd against the Company's anticipated R&D tax rebate for FY24. The loan facility has an establishment fee of 2% and bears interest of 1.38% per month with an initial maturity date of 30 November 2024 which can be extended for an additional 30 days upon agreement by the Lender.

8.	Estimated cash available for future operating activities	$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(378)
8.2	Cash and cash equivalents at quarter end (item 4.6)	1,121
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	1,121
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	2.9

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.

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

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.

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 October 2024

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.