ASX ANNOUNCEMENT

29 April 2024

March 2024 Quarterly Activities Report: Key advancements on Phase 2 SAMDE and positive engagement with the regulator to obtain FDA clearance for MEB-001

Highlights:

- **Positive meeting with the United States (US) Food and Drug Administration (FDA) regarding MEB-001, TrivarX's proprietary algorithm for the effective screening of a current Major Depressive Episode (cMDE)**
- **FDA meeting resulted in the establishment of a clearly defined route to regulatory approval for MEB-001 through the De Novo pathway**
- **Phase 2 Sleep Signal Analysis for Current Major Depressive Episode (SAMDE) study continues to progress well, with 305 subjects enrolled at the date of this report**
- **Collaboration partnership with Northern Michigan University (NMU) for the deployment of Stager, TrivarX's innovative sleep analysis software, as part of the University's ongoing sleep research programs**
- **Partnership will leverage TRI's core competencies in proprietary statistical modelling and machine learning to assist with ongoing improvements in neurophysiological monitoring practices at the NMU's Department of Psychological Sciences**
- **Further optimisation of the MEB-001 algorithm via the expansion of the training field to include data from Phase 1 of the SAMDE study**
- **Results from the analysis of 140 full-night and split-night polysomnography (PSG) tests from Phase 2 of the study further validate work carried out to-date**
- **Receipt of $888,829.41 during the quarter, in connection with TRI's status as an eligible recipient of the Australian Government's Research & Development (R&D) Tax Incentive program for the 2022/23 financial year**

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 ending 31 March 2024 (the "quarter").

During the quarter, the Company made key advancements on its clinical trial program, along with the establishment of a clear pathway to US regulatory approval for its proprietary MEB-001 algorithm which deploys advanced analysis of sleep data to effectively screen for instances of a current Major Depressive Episode (cMDE).

Clinical developments were accompanied by ongoing initiatives in support of the Company's innovative Stager software for rapid sleep analysis, highlighted by a research collaboration partnership with leading US tertiary institution Northern Michigan University (NMU).

Operational overview:

CLINICAL BUSINESS UNIT:

Positive engagement with US FDA following pre-submission meeting for MEB-001:

Developments for the Company's clinical operations were highlighted by a positive meeting with the United States (US) Food and Drug Administration (FDA) regarding the clearance of MEB-001.

MEB-001 is TrivarX's innovative, AI-backed algorithm to assist in the diagnosis of mood disorders 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.

Following the meeting, the FDA defined a clear path toward gaining regulatory clearance for MEB-001 via the De Novo pathway. The De Novo request provides a route to classify novel medical devices which meet designated FDA standards to provide a reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device.

Following the FDA meeting, TrivarX continued to advance its comprehensive Phase 2 Sleep Signal Analysis for Current Major Depressive Episode (SAMDE) study. As at the date of this report, 305 patients have been enrolled in the Phase 2 study which continues to progress in accordance with the stated timeline.

Additional data obtained from the study will be incorporated into the Company's ongoing dialogue with the FDA as part of the regulatory approval process. Upon completion of the trial, TrivarX will undertake further engagement with the FDA regarding the requirements of any additional validation studies required before submission.

Testing of proprietary MEB-001 algorithm delivers significantly increased performance metrics on Phase 2 SAMDE study data

During the quarter, TrivarX carried out extensive data analysis on results from Phase 1 of the SAMDE study to further optimise the proprietary MEB-001 algorithm.

The enhanced algorithm was subsequently tested on 140 full-night and split-night polysomnography (PSG) tests from Phase 2 of the study. Pleasingly, analysis of 140 subjects from the Phase 2 trial showed the application of the optimised algorithm resulted in an improvement across key performance parameters, comprising sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV).

Measure	Description	TRI Sample: 140 PSGs
Sensitivity	Ability for the test to correctly identify patients with the disease	86%
Specificity	Ability to designate an individual who does not have the diseases as negative	75%
PPV	Likelihood that a person who has a positive test result does have the disease	44%
NPV	Likelihood that an individual with a negative test result does not have the disease	95%

The results provide considerable confidence in work undertaken to date, and provides a foundation to generate further positive results as the Phase 2 SAMDE study advances towards completion. The

improved performance parameters also have the potential to support further positive engagement with the FDA as additional testing results are obtained.

NON-CLINICAL BUSINESS UNIT:

Research collaboration with Northern Michigan University (NMU):

Non-clinical operations in the period were highlighted by a strategic tertiary research partnership with Northern Michigan University, involving the deployment of TRI's Stager software.

Stager is an AI-based software solution that provides rapid data analysis on the relationship between brain waves (EEG), heart rate (ECG) and heart rate variability throughout the four key stages of sleep.

The terms of the agreement set out a framework for NMU and TrivarX to collaborate on sleep research programs where NMU will share sleep research data with the Company and TrivarX provides NMU with specific metrics that Stager extracts from sleep data. Located in Marquette, Michigan, NMU has established its credentials as a leading research institution with nationally recognised academic programs.

The collaboration aims to leverage the strengths of both NMU and TrivarX to pursue new approaches to neuromonitoring solutions, building from the university's decades of research experience using sophisticated neuromonitoring techniques.

NMU's specialisation in the field of neuroscience was complemented by the recent acquisition of a high-density electroencephalography (EEG) system for measuring affective states, particularly those associated with stress, anxiety, and depression. In turn, the University selected TrivarX as a research partner due to the Company's experience with mental health conditions and understanding of how sleep may play a critical role in effective diagnosis.

TrivarX expects that the findings from academic research will assist it to build out broader capability for the Stager software, and increase broader industry awareness resulting in the potential for further business development initiatives.

Management commentary:

Non-executive Chairman, David Trimboli said: *"The March quarter was highlighted by several key milestones with respect to our stated development strategy – most particularly the results from our scheduled FDA meeting in February where the Company achieved its objective to establish a clear pathway to US regulatory approval for the proprietary MEB-001 algorithm.*

"Following the meeting, TrivarX has continued to advance its comprehensive Phase 2 SAMDE Study, which now has over 305 patients enrolled and is scheduled for completion in the June quarter. As the Phase 2 study progresses, the Board and management team are preparing for a busy period of activity across the Company's clinical and non-clinical divisions, with ongoing FDA engagement for MEB-001 accompanied by research collaborations and business development initiatives for our innovative Stager software."

Corporate and Financial overview:

Financial overview:

During the quarter, TrivarX took receipt of $888,829.41 in connection with the Australian government's R&D Tax Incentive program for the 2022/23 financial year.

The refund payment relates to TrivarX's eligible expenditure in connection with the continuing development

of its Sleep Analysis of Major Depressive Episode (SAMDE) Clinical Study, and the ongoing development and commercialisation of the Stager software platform.

The Company continued to maintain a stringent focus on expenditure, with $409k spent on operating activities compared to the previous quarter of $462k, being a reduction of 11.5% quarter on quarter.

As at 31 March 2024, the Company retained a cash balance of $237,000 compared to $311,000 at the end of the prior quarter.

As per item 6 of the attached Appendix 4C cash flow report for the quarter, there were no 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	31 MARCH 2024

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	-	(85)
	(d) leased assets	-	-
	(e) staff costs	(72)	(213)
	(f) administration and corporate costs	(337)	(1,251)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	3	5
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives – 2023 R&D Tax Incentive	889	889
1.8	Other (provide details if material)	13	78
1.9	**Net cash from / (used in) operating activities**	**496**	**(577)**

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	(585)	(2,155)
	(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**	**(585)**	**(2,155)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	3,155
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	-	(348)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (payment of lease liabilities)	(20)	(94)
3.10	**Net cash from / (used in) financing activities**	**(20)**	**2,713**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	311	214
4.2	Net cash from / (used in) operating activities (item 1.9 above)	496	(577)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(585)	(2,155)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(20)	2,713
4.5	Effect of movement in exchange rates on cash held	35	42
4.6	**Cash and cash equivalents at end of period**	**237**	**237**

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	237	311
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)**	**237**	**311**

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

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	-	-
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)	496
8.2	Cash and cash equivalents at quarter end (item 4.6)	237
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	237
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	N/A

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: 29 April 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.