ASX ANNOUNCEMENT

30 October 2023

Quarterly Activities Report: Promising Phase 1 clinical trial results lay strong foundation for phase 2 Sleep Signal Analysis of Depression Burden (SAMDE) study

Highlights:

- **Phase 1 trial completed and confirms robust bidirectional relationship between mental illness and sleep**
- **Phase 1 trial tested 313 subjects across 12 sleep centres in five US states - Data obtained used towards ongoing algorithm development for mapping mood disorders**
- **Initial phase 1 results indicated an algorithm sensitivity of 71.65%, specificity of 71.43%, Positive Predictive Value of 35.38%, and Negative Predictive Value of 92.11% when tested within the development sample**
- **Preliminary phase 1 results exceed the current standard of care used to screen for Current Major Depressive Episode (cMDE) in individuals referred to sleep clinics for a polysomnography (PSG) assessment**
- **Phase 2 trial commenced – initially using Patient Reported Outcome (PRO) and now transitioned into Clinician-Reported Outcome (CRO) assessment, which is the ground truth**
- **Phase 2 CRO seeks to test at least 400 participants from 14 sleep centres across the US. The study is anticipated to be completed in Q2 CY2024 (dependent on patient enrolment)**
- **Phase 2 data to be used for final algorithm development and near-term FDA pre-submission objectives**
- **Multiple regulatory pathways being explored – TrivarX remains in discussions with regulatory lawyers regarding the best and most effective commercialisation pathway**
- **The possibility exists that MEB-001 diagnostic claim could be elevated from screening to diagnostic aid of a current mood disorder**
- **Completion of placement with new and existing institutional and professional investors to raise $2.25m**
- **Funding to be deployed to fast-track Phase 2 Sleep Signal Analysis for Current Major Depressive Episode study (SAMDE), FDA approval process for MEB-001, and commercial roll-out of Stager research tool in the US**
- **Cash balance of $808,000 as at 30 September with additional $824,775 (before transaction costs) received post quarter end following settlement of second tranche of placement**

Perth, Australia, and Minneapolis, USA: TrivarX Limited (‘the **Company’**) (ASX: TRI) is pleased to provide the following report on activities for the three months ended 30 September 2023 (the “quarter”).

TrivarX delivered several milestones during the period, including very promising results from phase 1 of its Sleep Signal Analysis for Current Major Depressive Episode study, the commencement of phase 2 of the trial and the completion of a $2.25m placement to fast-track growth initiatives.

Operational overview:

CLINICAL BUSINESS UNIT:

Phase 1 SAMDE preliminary trial results exceed standard of care to screen for the likelihood of a Current Major Depressive Episode (cMDE):

TrivarX reported promising results from the phase 1 SAMDE study, which was completed during the quarter. 293 participants delivered usable data for algorithm development, including 274 full-night studies and 19 split-night studies, from the initial phase 1. The Company's SAMDE study aims to continue to build and train TrivarX's innovative algorithm MEB-001 to assist in the screening for current mood disorders.

The preliminary results from sleep data collected indicated an algorithm sensitivity of 71.65%, a specificity of 71.43%, a Positive Predictive Value of 35.38%, and a Negative Predictive Value of 92.11% when tested within the development sample with a cross-validation protocol (see table below).

Initial Sensitivity results are promising concerning current US industry standards, where data compiled by Kaiser Permanente for the US Department of Health & Human Services[i] for clinician recognition of depression ranges from 21% to 76% of cases. Around 50% of these estimates fall above and the remainder fall below the international pooled average of 47.3%. Other studies have also reported a sensitivity of 49.3% and specificity of 81.1% for US primary care providers in accurately identifying cMDE.

Measure	Description	MEB-001 preliminary result	Current standard of care
Sensitivity	Ability for the test to correctly identify patients with the disease	**71.65%**	49.3%
Specificity	Ability to designate an individual who does not have the disease as negative	**71.43%**	81.1%
Positive Predictive Value	Likelihood that a person who has a positive test result does have the disease or condition.	**35.38%**	NA
Negative Predictive Value	Likelihood that an individual with a negative test result does not have the disease or condition	**92.11%**	NA

The Company is continuing to progress statistical analysis of all phase 1 data, which seeks to investigate the association between the preliminary predictors and depression. This includes an ongoing review of full-night and split-night data to identify predictors both study types and ongoing algorithm training.

Commencement of phase 2 trial:

Phase 2 of the trial seeks to test at least 400 participants from 14 sleep centres across the US. During the trial, clinicians will administer a Mini International Neuropsychiatric Interview (MINI) for each subject and provide an independent assessment of the underlying status of each subject to establish ground truth regarding current mood disorders.

The second phase of the SAMDE trial is a necessary step ahead of the upcoming clinical validation study, scheduled to commence Q1 FY2025, which will be an important part of the Company's FDA submission. Phase 2 also provides the opportunity for TrivarX to increase the key performance of MEB-001 when compared to the existing standard of care.

The company expects to complete Phase 2 in Q3 FY2024 (depending on patient enrolment), with preliminary results to be reported as they materialise.

Work towards pre-submission meeting with US FDA:

As previously advised, the Board and management continued to review regulatory approval pathways for MEB-001 in the US and have completed a number of internal steps toward a pre-submission meeting with the FDA.

The Company intends to schedule a pre-submission meeting with the regulator during Q3 FY2024, to seek agreement on the final clinical validation of its technology via the De Novo regulatory pathway. Board and management are confident that this meeting will provide a clear timeframe for the regulatory approval process.

NON-CLINICAL BUSINESS UNIT:

Ongoing development and commercial rollout of Stager:

Stager is an AI-based software solution that provides research groups with new data metrics in sleep studies. Stager utilises AI and spectral analysis of EEG and ECG signals. HRV analysis provides greater insights into the four stages of sleep, Stage has also been shown to have similar accuracy to human sleep raters and provides researchers with an innovative solution to also measure the objective relationships between brain waves (EEG), heart rate (HR) and heart rate variability (HRV) throughout sleep stages.

Stager is a research-only product. The company progressed discussions with several research organisations, which are anticipated to become beta testing sites in the near term. TrivarX will provide additional updates as agreements materialise.

The Company continued to deploy capital towards marketing and advertising with Stager, which has greatly assisted in broadening exposure with potential partners and customers.

Management commentary:

Non-executive Chairman, David Trimboli said: *"TrivarX has delivered another exceptional quarter of progress with respect to its stated clinical development pathway, leaving the Company well-positioned to achieve its next round of key milestones heading into the 2024 calendar year.*

"With results from the comprehensive phase 1 trial, TrivarX have demonstrated that its technology has the potential to deliver an improved level of care when compared with the current industry standard for diagnostic solutions that link instances of depression with sleep health. With that framework in place, the Board and management team are excited by what the Company can achieve in Phase 2 trials with respect to its FDA submission pathway.

"Our research efforts were assisted during the period by a strongly supported $2.25m capital raise, which allows the Company to continue to focus on its clinical development program. We look forward to providing more updates in the coming months as the phase 2 SAMDE trial progresses."

Corporate and Financial overview:

$2.25m in new funding secured to fast track clinical trials and Stager rollout:

TrivarX secured firm commitments to raise $2.25m through the issue of 1,500,000,000 new fully paid ordinary shares ("Shares") and an issue price of $0.0015 per Share ("Placement").

The Placement was well supported by a range of new and existing international and domestic institutional, professional and sophisticated investors and included commitments from Non-Executive

Chairman, Mr David Trimboli and other senior management personnel for $100,000 collectively. Mr Trimboli's participation was approved at the Company's General Meeting (refer ASX announcement 6 October 2023).

Funds raised will be used to fast track the Company's phase 2 SAMDE trial and progression of the De Novo regulatory pathway with the US FDA. Additional capital will also be deployed towards the commercial roll-out of Stager, which has the potential to provide a near term revenue stream.

The first tranche of 950,150,000 Shares issued under the Placement was issued pursuant to the Company's existing placement capacity under ASX Listing Rules 7.1 and 7.1A. (Tranche 1 Placement Shares). This represented approximately 18.45% of the shares on issue at that time. The unlisted free attaching options for the Tranche 1 Placement Shares were approved by shareholders at the Company's General Meeting held 6 October 2023.

The second tranche to issue 549,850,000 fully paid ordinary shares (Tranche 2 Placement Shares) at $0.0015 per share, together with one free attaching unlisted option to acquire a Share for every two Tranche 2 Placement Shares issued was also approved at the Company's General Meeting. The second tranche provided the Company with an additional $824,775 in funding, which is not recognised in the attached Appendix 4C.

Financial overview:

TrivarX continued to maintain a stringent cost focus during the quarter, which led to a reduction in staff costs from $127,000 during the June quarter to $76,000. Administration and corporate costs rose during the quarter, primarily due to the completion of the Company's Placement to fast track growth. Additional capital was deployed towards progression of Medibio's De Novo regulatory pathway with the US Food and Drug Administration (FDA) for MEB-001, as well as the commercial roll-out of Stager, MEB's disruptive AI-based software solution that provides research groups with new data metrics in sleep studies.

Cash at bank as at 30 September 2023 was $808,000. This has been bolstered during the current quarter following shareholder approval for the second tranche of its Placement, which has provided an additional $824,775 (before transaction costs). TrivarX's Board continues to monitor funding requirements to ensure sufficient working capital for its clinical trials, regulatory pathway and commercial deployment of Stager.

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.

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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

[i] Screening for Depression in Adults: An Updated Systematic Evidence Review for the U.S. Preventive Services Task Force. Prepared by: Kaiser Permanente Research Affiliates Evidence-based Practice Center, 2016, for the Agency for Healthcare Research and Quality, (U.S. Department of Health and Human Services).

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 2023

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	(77)	(77)
	(d) leased assets	-	-
	(e) staff costs	(76)	(76)
	(f) administration and corporate costs	(545)	(545)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
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)	23	23
1.9	**Net cash from / (used in) operating activities**	**(675)**	**(675)**

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	(770)	(770)
	(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**	**(770)**	**(770)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	2,330	2,330
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	(247)	(247)
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)	(37)	(37)
3.10	**Net cash from / (used in) financing activities**	**2,046**	**2,046**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	214	214
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(675)	(675)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(770)	(770)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	2,046	2,046
4.5	Effect of movement in exchange rates on cash held	(7)	(7)
4.6	**Cash and cash equivalents at end of period**	**808**	**808**

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	808	214
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)**	**808**	**214**

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)	(675)
8.2	Cash and cash equivalents at quarter end (item 4.6)	808
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	808
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.3

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?

No. The entity continues to undertake cost optimisation strategies to manage its liquidity and future expected net cash outflows. The entity also anticipates the receipt, subject to approval, of government grants and tax incentives related to the entity's research and development activities.

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?

Yes. During the quarter ended 30 September 2023, the entity raised $2,329,595 (before transaction costs) comprising of $904,370 to complete a share purchase plan and $1,425,225 via a Placement Tranche 1. Subsequent to the end of the quarter, the entity successfully raised $824,775 (before transaction costs) via a Placement Tranche 2 to complete a $2.25m capital raise via a Placement. The entity remains confident on raising further funds as and when the need arises.

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?

Yes. The entity does expect to be able to continue its operations and to meet its business objectives on the basis of the factors presented in 8.6.1 and 8.6.2.

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 2023

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.