ASX ANNOUNCEMENT

31 January 2024

December 2023 Quarterly Activities Report: Phase 2 Study - Sleep Signal Analysis for Current Major Depressive Episode (SAMDE) fast tracked to unlock growth potential

Highlights:

- **On-boarding completed across 15 sleep centres in the US as part of TrivarX's Phase 2 SAMDE study**
- **Aim of the Phase 2 trial is to detect the likelihood of a current major depressive episode (cMDE) in individuals referred to sleep clinics for PSG assessment utilising TRI's innovative, AI-backed algorithm TRI-001**
- **Total of 15 centres on-boarded in Phase 2 exceeds initial target of 14 – follows high level of in-bound enquiries from industry participants**
- **210 patients recruited during Phase 2 trial to date – TRI remains on track for completion in H1 CY2024**
- **Phase 2 study follows initial phase 1 results which showed similar results the current standard of care used to screen for cMDE in individuals referred to sleep clinics for PSG assessment**
- **Pre-submission meeting with US Food and Drug Administration (FDA) confirmed – in-person meeting to occur on 8 February 2024**
- **Research article published in 'Frontiers in Artificial Intelligence' highlighting the scientific validation of Stager technology.**
- **Publication of Company research expected to considerably broaden awareness of solution with industry partners and provides strong validation of work undertaken to date**
- **Change of Company name and consolidation finalised ahead of pending value catalysts including completion of Phase 2 SAMDE study and US regulatory approval process**
- **Cash at bank of $311,000 as at 31 December 2023, with pending R&D grant of over $800,000 expected to materialise in coming weeks provides financial flexibility**

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 2023 (the "quarter").

During the quarter, the Company delivered a number of corporate and operational achievements, which have laid a strong foundation for future growth and the completion of its Phase 2 of the Company's SAMDE study.

Operational overview:

CLINICAL BUSINESS UNIT:

15 sleep centres on-boarded to accelerate Phase 2 SAMDE study:

During the quarter, the Company completed on-boarding with a total of 15 sleep centres across the US, with the aim of accelerating Phase 2 of its SAMDE trial. Phase 2 of the study is being undertaken to continue to validate TrivarX's innovative algorithm (TRI-001) to assist in the screening and diagnosis of Current Major Depressive Episode (cMDE) in test subjects.

Completion of on-boarding and integration followed a high level of inbound interest from industry participants since the launch of Phase 2 of the study (refer ASX announcement: 4 September 2023). This was highlighted by engagement with Texas-based Comprehensive Sleep Medicine Associates ("CSMA") which added three additional sites and took the total number of centres being utilised in the trial to 15, exceeding TrivarX's initial target of 14.

TrivarX is seeking to test 400 patients during Phase 2 of the study. To date, the Company has enrolled 210 participants and remains on track for completion in H1 CY2024.

Under the Phase 2 trial protocol, clinicians will administer a Mini International Neuropsychiatric Interview (MINI) for each trial subject and provide an independent assessment of the underlying status of each subject to establish ground truth regarding cMDE status.

Phase 2 follows promising results from data collected during Phase 1, which included indicated 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 with a cross-validation protocol.

Initial Sensitivity results are promising with reference to 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	TRI 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

As previously advised, TrivarX is continuing to advance statistical analysis of all phase 1 data, which seeks to investigate the associated between the preliminary predictors and depression. This includes an ongoing review of full-night and split-night data to identify predicators both study types and ongoing algorithm training.

NON-CLINICAL BUSINESS UNIT:

Ongoing development and commercial rollout of Stager:

The Company continued to engage with key stakeholders including psychiatrists, neurologists, board certified sleep medicine physicians, and sleep researchers to progress the use of TrivarX's innovative Stager technology as part of the broader beta program.

Stager has a number of functionalities, which have the potential to considerably benefit industry participants. These include:

- Stager estimates sleep staging using probabilistic analysis instead of just naming the stage.
- Probabilistic analysis allows for quantifying ambiguity and sleep stability as a person transitions from one stage to the other.
- The probabilistic analysis provided by Stager can be used to display hypnodensity graphs, which can be crucial for certain sleep conditions.
- Stager provides HRV analysis throughout sleep staging.

The Company remains in well progressed discussions with potential counterparties and anticipates its planned beta testing program will considerably advance during the current quarter.

Company research published in leading scientific journal, Frontiers in Artificial Intelligence:

During the quarter, the Company published a research article entitled 'Enhanced sleep staging with artificial intelligence: a validation study of new software for sleep scoring' was published in a highly acclaimed scientific journal, Frontiers in Artificial Intelligence.

The research project was led by Dr. Massimiliano Grassi, TrivarX's Head of AI, Sivia Dacco, TrivarX' Psychology consultant, Prof. Giampaolo Perna, Head of the Psychiatry Clinical Team at Humanitas Hospital and TrivarX contributor, and Archie Defillo, M.D., Chief Medical Officer, TrivarX.

The piece highlights the potential for the Company's solution, as well as the ongoing and significant benefits which Stager can deliver. Further, publication in Frontiers in Artificial Intelligence provides considerable validation of the Company's work undertaken to date and will increase awareness in the target market.

Management commentary:

Non-executive Chairman, David Trimboli said: *"TrivarX has made exceptional operational and corporate progress during the quarter. This was primarily highlighted by work undertaken to advance our Phase 2 SAMDE study, which has generated pleasing sleep centre participation across the US, as well as healthy patient recruitment figures.*

"During the current quarter, TrivarX is focused on advancing the Phase 2 study towards completion, ongoing training of our innovative TRI-001 algorithm to potentially increase its measures, progressing an initial pre-submission meeting with the US FDA to better define a regulatory approval pathway and converting discussions with industry participants around Stager into a broader beta testing program. The Board and management look forward to providing additional updates on developments in the coming months."

Corporate and Financial overview:

Board and management transition:

Dr Thomas Young transitioned from his role as part-time CEO to a Non-Executive Director position during the quarter. Dr Young was appointed as CEO in September 2022 in a limited capacity. His management of day-to-day operation has played a central role in the success of the Company's operations to date.

Dr Young's transition to a Board role is in line with his intention to reduce executive duties. CEO duties are now shared by the Company's existing management team.

The shift has also allowed the Company to commence an executive search for a full-time CEO that can lead Trivarx through the next phase of its stated growth trajectory. A number of potential candidates have been earmarked for the role, each with exceptional experience in the US healthcare and sleep sectors. Additional updates will be provided as appointments are made in the coming months.

Change of company name and ASX code:

At the Annual General Meeting held on 6 October 2023, a resolution was passed to change the Company's name from Medibio Limited to TrivarX Limited. The Company commenced trading under the new name and ASX code of TRI at the commencement of trade on 16 October 2023.

The new name represents the Company ongoing commitment to realise a new level of integrated care at the nexus of physical health, mental health and sleep health by delivering a clinically-backed sleep diagnostics solution that provides an objective assessment of how sleep health is correlated with other health variables.

As part of the name change, the Company's digital assets and other marketing collateral were also updated.

Financial overview:

The Company continued to maintain a stringent focus on expenditure, highlighted by a 41% reduction in new cash used in operating activities when compared to the previous quarter (Q1 FY2024: $675,000). The decrease was primarily due to a reduction in marketing and advertising costs, as well as lower administration and corporate costs.

As at 31 December 2023, the Company retained a cash balance of $311,000. TrivarX also expects to received an R&D Tax Rebate in the coming weeks, with an anticipated value of ~$800,000. Given the Board's ongoing focus on reducing operational expenditure, the Company is confident that it has sufficient financial flexibility to continue its Phase 2 SAMDE trial, pursue its stated regulatory pathway with the US FDA and progress the 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.

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

[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	31 DECEMBER 2023

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	(8)	(85)
	(d) leased assets	-	-
	(e) staff costs	(65)	(141)
	(f) administration and corporate costs	(369)	(914)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	2	2
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)	42	65
1.9	**Net cash from / (used in) operating activities**	**(398)**	**(1,073)**

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	(800)	(1,570)
	(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**	**(800)**	**(1,570)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	825	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	(101)	(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)	(37)	(74)
3.10	**Net cash from / (used in) financing activities**	**687**	**2,733**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	808	214
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(398)	(1,073)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(800)	(1,570)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	687	2,733
4.5	Effect of movement in exchange rates on cash held	14	7
4.6	**Cash and cash equivalents at end of period**	**311**	**311**

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	311	808
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)**	**311**	**808**

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)	(398)
8.2	Cash and cash equivalents at quarter end (item 4.6)	311
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	311
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	0.8

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 Company remains committed to stringent cost controls around the operating expenses. In addition, whilst there are once-off costs to come through in the March quarter related to the Company's FDA submission, the Company expects these increases to be fully offset by the receipt of government grants and tax incentives related to the entity's research and development activities which was expected in the December 23 quarter but receipt is now expected in the March 24 quarter and amounts to circa $800,000.

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 31 December 2023, the entity raised $824,775 (before transaction costs) to ultimately 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: 31 January 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.