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ASX ANNOUNCEMENT

31 July 2024

Quarterly Activities Report: Advancement and subsequent completion of Phase 2 SAMDE trial brings TrivarX closer to FDA approval

Highlights:

- **Phase 2 Sleep Signal Analysis for Current Major Depressive Episode (SAMDE) study completed with 400 patient mark met subsequent to the end of the period**
- **Phase 2 SAMDE study utilises Company's proprietary AI-driven algorithm to assist with the effective screening of a current Major Depressive Episode (cMDE)**
- **Subsequent to the end of the period, MEB-001 performance results from Phase 2 SAMDE study reported high performance, marking a significant achievement in the Company:**
    - **Sensitivity: 87% (95% CI 73-95%)**
    - **Specificity: 72% (95% CI 66-77%)**
    - **Positive Predictive Value: 35% (95% CI 27-45%)**
    - **Negative Predictive Value: 97% (95% CI 93-99%)**
- **Results of phase 2 SAMDE study to inform ongoing engagement with United States (US) Food and Drug Administration (FDA) and De Novo clearance for MEB-001**
- **Strategic advisor, W Drew Palin, M.D. appointed to advance commercial opportunities - Mr Palin is a seasoned healthcare executive with over 30 years' experience**
- **Dr Tony Keating appointed as Executive Director post quarter end - Dr Keating is a healthcare executive, having co-founded ResApp Health and leading it through commercialisation, culminating in a $180m acquisition by global biopharmaceutical company Pfizer in 2022**
- **Completion of $2.5m capital raise with $725,000 received subsequent to the end of the quarter and R&D Tax Incentive valued at approximately $700,000 expected to materialise shortly – Takes pro forma cash balance to ~$2.2m**

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 June 2024 (the "quarter").

During the quarter, the Company continued to advance its Phase 2 Sleep Signal Analysis for Current Major Depressive Episode (SAMDE) study, which utilises TrivarX's proprietary AI-driven algorithm, MEB-001. The study aims to continue to validate its innovative algorithm (MEB-001) to assist in the screening of a current Major Depressive Episode (cMDE) in test subjects. The Company also strengthened its US footprint, with the appointment of a seasoned healthcare executive in an advisory capacity.

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Operational overview:

CLINICAL BUSINESS UNIT:

Ongoing work and completion of Phase 2 SAMDE study:

The Company significantly advanced its Phase 2 SAMDE study during the period, which was completed subsequent to the end of the quarter.

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 a sleep clinic.

Positive results from Phase 2 SAMDE study:

Subsequent to the end of the period, the Company reported promising algorithm performance results from its Phase 2 study. A total of 400 patients were recruited across 15 sleep centres in the US. Out 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. Notably, 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 that MEB-001 reported promising performance across key parameters including sensitivity of 87% (95% CI 73-96%), specificity of 72% (95% CI 66-77%), positive predictive value (PPV) of 35% (95% CI 27-45%) and negative predictive value (NPV) of 97% (95% CI 93-99%) (refer table below).

Measure:	Description:	MEB-001 performance:
Sensitivity	Ability for the test to correctly identify patients with the disease	**87% (95% CI 73-95%)**
Specificity	Ability to designate an individual who does not have the disease as negative	**72% (95% CI 66-77%)**
Positive Predictive Value (PPV)	Likelihood that a person who has a positive result does have the disease or condition	**35% (95% CI 27-45%)**
Negative Predictive Value (NPV)	Likelihood that a person who has a negative result does not have the disease or condition	**97% (95% CI 93-99%)**

The results show a significant increase in sensitivity from 71% in Phase 1 to 87% in Phase 2, which demonstrates MEB-001's ability to correctly identify people with cMDE. The NPV of 97% validates MEB-001's potential as a screening test, with the likelihood of having depression when testing negative to be less than 3%. The PPV of 35% places MEB-001 at the upper end of existing depression screening tools.

These results provide considerable validation of MEB-001 and its ability in the screening and diagnosis of a current Major Depressive Episode (cMDE) in test subjects.

NON-CLINICAL BUSINESS UNIT:

Appointment of seasoned healthcare executive as strategic advisor:

The Company bolstered its management team with the appointment of W. Drew Palin M.D. as a strategic advisor. Under the role, Mr Palin will advance a number of corporate opportunities around partnership agreements, licencing opportunities and other commercialisation initiatives.

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Mr Palin is a seasoned healthcare executive and an innovative entrepreneur with over 30 years of experience in the medical technology sector. He is currently Chief Business Officer of American Gene Technologies International Inc. and has a number of senior positions in the US healthcare sector, including Medical Innovation Officer at Preventice (acquired by Boston Scientific for ~USD$925m+) and Chief Development Officer at leading insurance provider Blue Cross of Northeastern Pennsylvania. Mr Palin is also a seasoned entrepreneur, founding AI-patient access company Intellivisit Solutions and claims-based health software business ThinkMED. These roles have provided him with extensive experience in medical technology commercialisation.

Participation at SLEEP 2024:

During the quarter, the Company participated in SLEEP 2024, which is an annual meeting of the Associated Professional Sleep Societies. The event is a joint venture between the American Academy of Sleep Medicine and the Sleep Research Society.

The conference was held in Houston, Texas between 1 June and 5 June and allowed TrivarX a number of opportunities to present its technology to researchers, device companies, distributors and other industry participants. The Company advises that this has led to a number of follow up engagements.

Appointment of Dr Keating as Executive Director:

Subsequent to the end of the period, TrivarX further strengthened its Board and management with the appointment of Dr Tony Keating, effective 29 June 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 was the co-founder and CEO of ResApp Health, a digital health company which successfully developed a groundbreaking smartphone technology for accurately diagnosing respiratory diseases based on cough analysis.

Dr Keating led the ResApp team through the company's technology commercialisation phase, commencing with a successful R&D phase through to global regulatory approvals and commercial partnerships, before overseeing the sale of the company to Pfizer in 2022 for $180m. Following the acquisition, he transitioned to the role of Vice President at Pfizer to manage the integration of ResApp's business.

Prior to co-founding ResApp, Dr Keating was the Director of Commercial Engagement at UniQuest, the commercialisation arm of The University of Queensland (UQ) which specialises in industry-university collaborations for the UQ's in-house network of 7,000 world-class researchers.

Concurrently, the Company advised Dr. Thomas Young had resigned from his position as Non-Executive Director. The Board and management thank Dr Young for his contribution to the Company and wish him well for future endeavors.

Management commentary:

Non-executive Chairman, David Trimboli said: *"During the quarter and subsequent to the end of the period, the Company has delivered on a number of major and value accretive milestones. This includes the Phase 2 SAMDE clinical study results, which highlight the effectiveness of MEB-001 and provides us with considerable confidence in the technology's potential.*

"It is important to reiterate that there is currently no cMDE screening undertaken in sleep centres across the globe. These results highlight MEB-001's potential to become the first and to capitalize on this strategy, the Company also welcomes Dr Tony Keating as a part-time Executive Director and Drew

Palin as a strategic consultant. Both have extensive experience in the regulatory approval process, as well as commercialisation. We look forward to leveraging their respective skillsets to unlock value for shareholders in the near term."

Corporate and financial overview:

Completion of $2.5m raise to advance clinical trials and regulatory engagement:

TrivarX received firm commitments from a range of local and international professional, institutional and sophisticated investors to raise $2.5m through the issue of 100,000,000 new fully paid ordinary shares ('Shares') at an issue price of $0.025 per Share ('Placement').

The Placement was conducted in two tranches. The first tranche of 70,970,745 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). The second tranche of 29,029,255 Shares (Tranche 2 Placement Shares) was approved for issue by shareholders at a General Meeting held on 5 July 2024. The issue of these Shares resulted in $725,731 in capital being received by the Company, which is not included in the attached Appendix 4C.

Financial overview:

During the quarter, the Company remained focused on reducing expenditure which resulted in $273,000 spent on operating activities, compared to $409,000 in the previous quarter. As at 30 June 2024, the Company retained $848,000, which has since been bolstered by the additional $725,731 received subsequent to the end of the period. The Company also expects to receive an R&D Tax Incentive of approximately $700,000 during H2 CY2024.

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

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Appendix 4C

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

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Name of entity	
TRIVARX LIMITED	
ABN	**Quarter ended ("current quarter")**
58 008 130 336	30 JUNE 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 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	(47)	(260)
	(f) administration and corporate costs	(228)	(1,479)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	2	7
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
1.8	Other (provide details if material)	-	78
1.9	**Net cash from / (used in) operating activities**	**(273)**	**(850)**

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	(694)	(2,849)
	(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**	**(694)**	**(2,849)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	1,774	4,929
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	(130)	(478)
3.5	Proceeds from borrowings	55	55
3.6	Repayment of borrowings	(61)	(61)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (payment of lease liabilities)	(29)	(123)
3.10	**Net cash from / (used in) financing activities**	**1,609**	**4,322**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	237	214
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(273)	(850)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(694)	(2,849)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,609	4,322
4.5	Effect of movement in exchange rates on cash held	(31)	11
4.6	**Cash and cash equivalents at end of period**	**848**	**848**

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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	848	237
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)**	**848**	**237**

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		

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8.	Estimated cash available for future operating activities	$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(273)
8.2	Cash and cash equivalents at quarter end (item 4.6)	848
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	848
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	3.1

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.

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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 July 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.

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