Commercialising AI-driven solutions to objectively screen for mental health conditions

Investor presentation – May 2024

(ASX: TRI)

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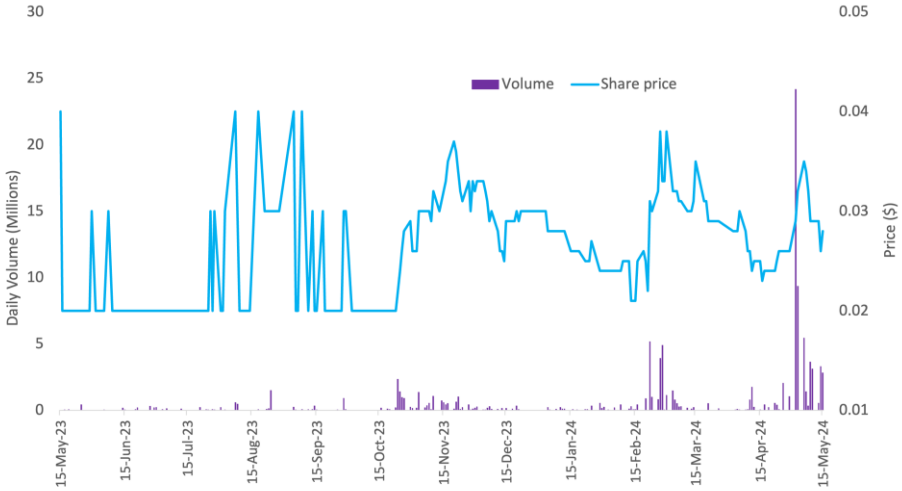
Corporate overview

Corporate snapshot	
ASX code:	TRI
Shares on issue:	~409.6m
Market capitalisation (at $0.027 per share): (as at 21 May 2024)	~A$12.3m
Options on issue:	~158.3m
Debt:	Nil

Board and management	
Non-Executive Chairman	Mr David Trimboli
Chief Operating Officer	Mr Kai Sun
Non-Executive Director	Dr Thomas Young
Non-Executive Director	Mr Chris Ntoumenopoulos
Chief Medical Officer	Dr Archie Defillo
Head of Artificial Intelligence	Mr Massimiliano Grassi

Share price and volume (May 2023– May 2024)**



Major shareholders	
FIL Investment Management (Hong Kong) Limited	8.01%
Top 20:	**41.52%**

**Based on consolidation/split announced to ASX on 18 October 2023

Company overview

A US-based company pioneering the use of AI to aid in the early detection of mental health conditions

Commercialising AI-driven, scientifically-backed diagnostic tools to objectively screen and assist in the diagnosis of mental health conditions

MEB-001 utilises biometric Data, EEG (Brain), ECG (Heart Rate) and HRV recordings collected during in-clinic sleep studies to screen for current Major Depressive Episode (cMDE)

Extensive Phase 2 Sleep Analysis of Depressive Burden Study is ongoing across 15 US-based sleep centres. In an interim analysis cMDE reported sensitivity of 86% and specificity of 75%

Defined pathway to US FDA regulatory approval via De Novo submission – Company has held multiple pre-submission meetings with the US FDA and gained positive feedback to date

Through its clinical trials, TrivarX has now built the world's largest database of sleep study data labelled with patient's mental health status

The US mental health epidemic

Exploring the robust relationship between sleep and mental health in the US

- **1 in 5 American adults (~57m people) experience a mental illness**
- **1 in 25 US adults live with a serious mental health condition including major depression, bipolar and schizophrenia**
- **Nearly 50% of serious mental health disorders are untreated**
- **Mental health misdiagnosis is rife – Social anxiety: 97.8%, Bipolar: 92.7%, Panic disorder: 85.5%**
- **Concurrently, data shows 75% of people with diagnosed depression also suffer from disrupted sleep patterns**

A scientifically backed approach

Underpinned by leading management, extensive experience and industry validation

Extensive industry validation:

- Since the early 2000s, TRI's dedicated scientific personnel have built evidence to support that EEG, EKG and HRV data collected during sleep can be used to assist with the diagnosis of mental health conditions via AI and machine learning
- 13 peer reviewed publications and top congress scientific presentations
- Three clinical trials completed and a well progressed Phase 2 clinical trial for current Major Depressive Episode (cMDE) expected to complete mid CY2024
- TRI boasts data from over 880 subjects including 7,000 hours of sleep recording which includes concurrent mental health evaluation

Leading Scientific expertise:

Archie Defillo M.D. – Chief Medical Officer

- 25 years clinical experience with neurological diseases and a trained neurosurgeon
- 70+ publications on topics predominantly based on heart rate studies
- Dedicated to advancing TRI's knowledge of heart rate variability and autonomic modulation

Massimilano Grassi PhD – Head of AI

- 15 years experience as a data scientist in mental health field with an extensive background in psychology
- Ph. D in Supervised Machine Learning for Clinical Psychiatry
- Focused on the development of machine learning algorithms using sleep as the window into mental health.

Product overview

Interrelated product suite with significant commercialisation and scale up potential

Stager

- AI-based software that provides researchers with unique HR and HRV metrics combined with hypnodensity graphs from sleep study data
- Insights on the 4 key sleep stages in 30 minutes – Industry standard currently ~2 hours
- Provides unique data beyond current sleep staging tools in the market
- Data capture further informs MEB-001 and accelerates the development of additional mental health-sleep algorithms

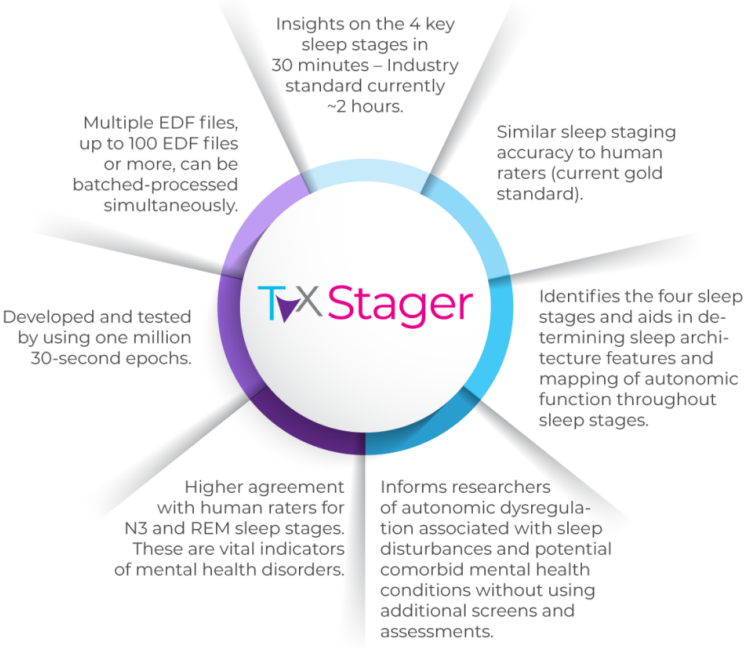
MEB-001

- An innovative machine learning and AI-backed algorithm to screen sleep study patients for cMDE
- Uses Biometric Data, EEG (Brain), ECG (Heart Rate) and HRV recordings collected during-in-clinic sleep studies
- Identifies a patient with cMDE with 86% sensitivity and 75% specificity
- Defined route to market via FDA's De Novo pathway

Stager – Uptake and ongoing commercialisation

Stager solution unlocks potential to establish a strong in-market presence while strengthening MEB-001

- Data collection from partnerships and deployments further strengthens MEB-001 by further informing company's core algorithms
- Product target markets include research institutions, universities and pharmaceutical companies for use in R&D, clinical trials and other projects
- Partnerships provide significant third-party validation and further promote company's market presence
- Ongoing data collection via Stager allows company to broaden solution offering across additional need states
- Partnership with Northern Michigan University (NMU) established in February 2024 - Marked first company data research agreement
- Discussions with additional large university research groups and government research agencies are well progressed



MEB-001 – redefining sleep and depression

MEB-001 has the potential to become the standard depression symptom screening tool within US Health Systems

- TrivarX's proprietary algorithm is being developed as a tool to be used to screen and aid in the diagnosis of cMDE
- Current algorithm performance demonstrates an 86% sensitivity and 75% specificity with a 44% PPV and 95% NPV
- Algorithm only requires data collected from a standard sleep study:
    - ~60-70% of patients with Sleep Apnea (SA) have depressive symptoms
    - Circa 39m US adults suffer from Obstructive Sleep Apnea
- Phase 2 SAMDE trial well progressed and US FDA approval process being advanced to unlock value and commercialisation potential
- There is no standard depression symptom screening carried out in sleep centres in the US or globally – highlighting current market opportunity

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Clinical	Regulatory
Early Clinical ✓	
Feasibility Phase 1 ✓	FDA pre submission meeting 1 ✓
Feasibility Phase 2 *(underway)*	FDA pre submission meeting 2 *(scheduled in Q1 FY25)*
Pivotal	FDA De Novo submission
	FDA Clearance

MEB-001 – Promising Phase 1 trial results

- Sleep Signal Analysis of Depression Burden (SAMDE) Study Phase 1 clinical trial completed in July 2023
- Aim of SAMDE Phase 1 trial was to detect the likelihood cMDE in individuals referred to sleep clinics for polysomnography (PSG) assessment using TRI's innovative AI-backed algorithm
- Results taken from 313 subjects across 12 sleep centres in five US states – Findings highlighted a robust bidirectional relationship between mental illness and sleep

Phase 1 results highlight:

72%	71%	91%
Sensitivity	**Specificity**	**Negative predictive value**
The ability for the test to correctly identify patients with the disease	**The ability of the test to correctly identify patients without the disease**	**The ratio of true negatives compared to all those who had negative test results**

✓ **Preliminary SAMDE Phase 1 trial data demonstrated a 7 out of 10 success rate identifying cMDE**

✓ **Current screening accuracy ranges from 21% to 76% with a pooled average of 46%***

*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).

Phase 2 SAMDE trial and interim results

- Phase 2 trial aims to detect likelihood of a cMDE using Clinician Reporting Outcomes (CRO) assessment in individuals referred to a sleep clinical for PSG assessment using TRI's algorithm
- Phase 2 to test up to 400 participants from 15 US sleep centres – expected to be completed shortly (dependent on enrolments)
- Results to be used for final algorithm development, which includes determining overall accuracy and algorithm performance
- 317 of 400 patients recruited with completion expected in coming weeks

When MEB-001 was tested on the first 140 patients from Phase 2, it showed:

86%

Sensitivity

The ability for the test to correctly identify patients with the disease

75%

Specificity

The ability of the test to correctly identify patients without the disease

95%

Negative predictive value

The ratio of true negatives compared to all those who had negative test results

Commercial model and go to market strategy

Potential for rapid adoption of MEB-001 through strategic partnerships with US sleep labs

Commercial model

- Currently, there are ~980,000 sleep tests done in the US per annum
- MEB-001 is designed to integrate into all existing sleep lab software and workflow systems
- Highly scalable SaaS business model – No upfront cost, no additional capex required and seamless integration into current sleep lab technology
- Additional testing capabilities expected to significantly increase testing rates and drive additional revenue for sleep clinics
- Sleep clinic customers have the potential to increase their service offering following potential CMDE diagnosis via MEB-001, unlocking additional sales

Go to market strategy

- Leverage existing partnerships with sleep research centres to convert early adopters through trial partnerships
- Pursue validation of SAMDE clinical pathway via publication of research results in peer-reviewed scientific journals
- Expand advisory panel through direct engagement with leading experts in the fields of sleep research and mental health
- Targeted industry awareness campaigns through effective marketing materials and presentations at select conferences, including the AASM (American Academy of Sleep Medicine) and the World Sleep Congress

Multiple near-term value catalysts

- Finalisation of comprehensive Phase 2 SAMDE study to validate data – study which has over 300 patients enrolled to-date and is advancing in accordance with its stated completion timeline (June quarter 2024).
- Ongoing dialogue with the US Food & Drug Administration (FDA) following successful pre-submission meeting in February 2024, which formally established a pathway to US regulatory clearance for MEB-001 through the De Novo classification for novel medical devices.
- Discussions underway with several third-party providers, including leading universities and government research agencies, for the commercial deployment of Stager technology as a complement to existing sleep research and analysis practices.
- Ongoing training and refinement of the MEB-001 algorithm to further de-risk the regulatory process as TRI follows its stated strategy to pursue FDA clearance through the De Novo pathway.
- Targeted strategies for direct engagement with medical industry groups and representative bodies for US GPs, to educate sector professionals who currently administer depression screening tools on the attributes of MEB-001 in line with ongoing clinical milestones

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Appendix 1: Intellectual Property and patents

Four patents granted and currently active

1

US Pat. No. 10,912,508 - Issued 09 Feb 2021.
Method and system for assessing mental state

2

US Pat. No. 10,638,965 - Issued 05 May 2020.
Method and system for monitoring stress conditions.

3

US Pat. No. 10,039,485 - Issued 07 Aug 2018.
Method and system for assessing mental state.

4

US Pat. No. 9,861,308 - Issued 09 Jan 2018.
Method and system for monitoring stress conditions.

Appendix 2: Clinical research and technology

Supervised Artificial Intelligence

Data has been taken from 400+ subjects to date:

- Prospective data collection – remains ongoing
- Combining EEG and ECG enables the technology to map the connectivity between brain and heart activity throughout sleep stages
- TRI has identified novel sleep biomarkers that map a person's mood disorder

Clinical Study	SLEEP	SADB	SAMDE PI	SAMDE PII	Clinical Validation
Status	Complete	Complete	Complete	Underway	Planned
Software Module(s)	SEEG SHRV	SEEG SHRV	SEEG SHRV DMI	SEEG SHRV DMI	SEEG SHRV DMI
Location	USA	USA	USA	USA	USA
Study Size	40	329	313	Up to 400	TBD
Study Dates	2019	2019	2021	2023	2024 (Planned Study Start)
Subjective Data	None	BDI PHQ-9	MINI (PRO) PHQ-9	MINI (CRO) PHQ-9	MINI (CRO) PHQ-9
Value Delivered	Internal POC for Supervised AI	Early AI performance data vs. PRO	Enhanced PRO w/reduced noise and broadened symptoms	Use of MINI (CRO) as proposed ground truth	US FDA clearance
Objective Data	EEG ECG	EEG ECG	EEG ECD Socio-demographics	EEG ECG Socio-demographics	EEG ECG Socio-demographics Risk Factors
Hardware	In-Lab Polysomnography				
Focus	Autonomic Function	Depressive Symptoms/Severity			Depressive Symptoms +Disorder Risk