TrivarX

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

November 2023

(ASX: TRI)

Authorised for release by the Board of TrivarX Limited

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A US-based medical technology company



Commercialising **AI-driven**, evidence based screening products and diagnostic tools to assist in the screening and long-term monitoring of mood disorders

Research is focused on the **robust bidirectional relationship between mental illness and sleep disturbances**

Developing a more cost-effective clinical solution to benefit patients, clinicians, hospitals and payers and drive better patient outcomes

Stager sleep software product aimed at sleep research organisations in the US to roll-out in coming months – targeting a US\$9.2Bn sleep medicine market



MEB-001 – A software as a medical device (SaMD) driven by objective information for the screening and long term monitoring of mood disorders. In clinical development with plans for market authorisation via the FDA – multiple pathways being assessed



Growth trajectory to be underpinned by an **advanced clinical trial program** and **new Board and management** which includes **US-based mental health, sleep and healthcare professionals**

Major market opportunity and drivers



US sleep clinic market growth:

+ US\$15.92Bn

Market value by 2028 at a CAGR of 8.2%

Depression screening in the US:

Only **1.4%** of US outpatients are

screened for depression at the

primary care level

~66% misdiagnosis rate in primary care

and depression screening is <u>not</u> part of clinical practice in sleep clinics **Sleep disorders in the US:**

60m people suffer from poor sleep quality

40m meeting diagnostic criteria for sleep disorder diagnosis

Total screening market:

Standardised PH-9 screening tool - incumbent for 20 years with no innovation

Overestimates prevalence of depression and leads to over-prescription from primary care Correlation between depression and sleep disorders:

75% of people with diagnosed depression suffer from disrupted sleep patterns

The TrivarX solution:

Developing clinical solutions to benefit patients, clinicians, hospitals and payers dealing with mood disorders

Taking mental health diagnosis from subjective to objective

Innovative solutions



Stager

SLEEP HEALTH

MEB-001

- Al-based software solution that provides researchers A med with new data metrics in sleep studies mood
- Insights on the 4 key sleep stages in 30 minutes Industry standard currently ~2 hours
- Similar accuracy to human sleep raters which is the current gold standard)

- A medical device to screen sleep study patients for the mood disorders
- Uses Biometric Data, EEG (Brain), ECG (Heart Rate) and HRV (Heart Rate Variability) recordings collected during in-clinic sleep studies
- In clinical development, with plans for market authorisation via the FDA

Stager

A disruptive sleep research tool aimed at the burgeoning US sleep research industry

Deploys AI, machine learning technology and deep learning algorithms – product aimed at sleep research organisations across the US

Identifies the four important sleep stages of a subject; aids in the determination of sleep architecture features and the mapping of autonomic functions throughout sleep stages

Developed and tested by using one million 30 second sleep intervals (epoch) from more than 1,000 PSG studies

Provides a solution for sleep researchers to measure the objective relationship between brain waves (EEG), heart rate (ECG) and heart rate variability throughout the four sleep stages

Solution provides information not available elsewhere with similar accuracy to human raters

Large near-term market opportunity of 4,700 sleep clinics across the US with an estimated US\$520m to be spent on research in 2023 – Multiple targets identified with pricing model in development



Stage :

Stage 4 (Deepest Siles

2





Stager's unique features and benefits



Speed:



Human rated sleep scoring takes two or more hours while Stager sleep scoring and HRV calculation only takes 30 minutes - Up to 100 files, or more, can be batch processed

Unique features and benefits:

Feature:



Feature:

Closer alignment with human raters for N3 Stage and REM sleep stages, which are key indicators of mental health

Accuracy:



Stager has been shown to have similar accuracy to human raters (current gold standard)

Benefit:



Alternations in HRV are associated with autonomic dysregulation

Benefit:



Informs researchers of autonomic dysregulation associated with sleep disturbances, without using additional screens and assessments

MEB-001



Potential to become the first FDA approved medical device to screen and monitor for Current Major Depressive Episode (cMDE) using objective data from in-clinic sleep studies



Only 1.4% of all adult outpatient care visits in the US are screened for depression – MEB-001 aims to provide a standardised solution for effective and increased depression screening



MEB-001 extracts and analyses Biometric Data, EEG (Brain) signals and ECG (Heart Rate and Heart Rate Variability) signals obtained from in-clinic sleep studies to screen for current major depressive episode (cMDE)



Clinical validation will compare MEB-001 against ground truth for the presence of cMDE in accordance with FDA requirements – first pre-submission meeting with the FDA expected to occur in Q1 CY2024

Clinical flow to provide future standardised solutions for additional health screening and diagnostic tools



Preliminary SAMDE Phase 1 clinical trial results taken form over 313 patients across sleep centres in five US states have laid a very strong foundation for Phase 2 testing and ongoing algorithm development

Clinical research and technology



Supervised Artificial Intelligence

Data has been taken from 400+ subjects to date:

- Prospective data collection remains ongoing
- Sleep is the window to mental health
- 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 Al	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

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

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 of a current major depressive episode (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

Early test results for accuracy highlight:

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

Sensitivity

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

Negative predictive value

91%

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%*



71%

Specificity

72%

Phase 2 SAMDE trial underway

- 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 14 US sleep centres expected to be completed Q2 FY2024 (dependent on enrolments)
- Results to be used for final algorithm development, which includes determining overall accuracy and algorithm performance

Progress to date and near term value catalysts (calendar):



Q1/Q2 2024:

InvarX

Commercial adoption strategies for MEB's solutions



Licencing opportunities:

- Initial focus to distribute Stager technology on a SaaS licencing model to research groups
- Discussions with target groups underway and agreements anticipated H2 CY2023
- Estimated US sleep research spend in 2023: US\$520m (US NIH data)

Group Purchase Organisations (GPO):

- Build distribution networks with GPOs providing broader access to the US healthcare industry as the primary source of demand for collective purchasing solutions
- Align rollout of Stager software with GPOs on a region-by-region basis to broaden footprint
- Leverage existing GPO networks for pending rollout of MEB-001 screening tool (post regulatory approval), followed by additional services as clinical pathway develops

Integration with hardware manufacturers:

- Layer software solution with existing hardware providers and manufacturers of EEG (Brain) and ECG (Heart) scanning and biometric analysis products
- Multiple targets identified for broader commercial integration of both solution offerings



Antegrated Care Model

Investment summary

A significant opportunity to disrupt the US healthcare sector and provide better patient care and cost efficiencies A scientifically based product portfolio with a defined commercialisation pathway and an established regulatory route via the US FDA

Targeting major market opportunities in the US, in need of innovation and a solution to undiagnosed and misdiagnosed mental health conditions



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Considerable potential to expand clinical offerings and functionality of Stager via research partnerships and MEB-001 through ongoing algorithm development



Underpinned by a Board and management team with a proven track record in the US and global healthcare markets

Multiple near term value catalysts pending:

- Stager solution in use with research partners Q4 CY2023 / Q1 CY2024
- Completion of Phase 2 SAMDE trial and results early CY2024
- FDA pre-submission meeting Q1 CY2024

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Appendix 1: Corporate overview



Corporate snapshot	
ASX code:	TRI
Shares on issue:	~335.7m
Market capitalisation (at \$0.03 per share): (as at 9 November 2023)	~\$10.1m
Options on issue:	~170.8m
Cash at bank:	~\$1.63m
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* (Nov 2022 – Nov 2023)



Тор 20:	55.94%
FIL Investment Management (Hong Kong) Limited	9.77%
Major shareholders	

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

Appendix 2: Intellectual Property and patents

Four patents granted and currently active



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

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

US Pat. No. 10,912,508 - Issued 09 Feb 2021.

Method and system for assessing mental state

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

Appendix 3: Accomplished Board and management

Board of Directors:

David Trimboli – Non-Executive Chairman

- Founder of Seefeld investments, an Australian-based investment firm with offices in London and Switzerland
- Has previously held roles with major conglomerates including senior roles at Glencore
- Director of multiple ASX-listed companies

Dr Tom Young – Non-Executive Director

- 45 years' medical experience and seen as an innovator and thought leader in consumer directed healthcare
- Previously the Medical Director of Idaho Medicaid and remains active in the formation of medical and mental health policy
- Held senior role at US health technology company, Connextions, acquired by Optum Health, a division of United Health Group

Chris Ntoumenopoulos – Non-Executive Director

- Managing Director of Twenty1 Corporate, an Australian based corporate advisory firm focused on healthcare and technology companies
- Previously held ASX directorships with leading healthcare companies including Race Oncology Limited and ResApp Health Limited

Management:

Archie Defillo – Chief Medical Officer

- 25 years clinical experience with neurological diseases and a trained neurosurgeon
- Holds 50+ publications on topics predominantly based on heart rate studies
- Dedicated to advancing MEB's knowledge of heart rate variability and autonomic modulation

Massimilano Grassi – Head of Al

- 15 years experience as a data scientist in mental health field with an extensive background in psychology
- Focused on the development of machine learning algorithms for the identification of sleep staging and depression

Dave Danielson – Chief Marketing Officer

- 40 years' experience specialising in healthcare and technology
- Recently VP of sales at US-based, VAR and increased sales from US\$25m to US\$72m over a seven-year period
- Multiple other senior roles at industry leading global companies

IrivarX

Appendix 4: Citations



Projected Growth: \$9.20B/2021 to \$15.92B/2028 with CAGR of 8.2%:

https://www.fortunebusinessinsights.com/u-s-sleep-disorder-clinics-market-106600

Just 1.4% depression screening rate for all adult outpatient care visits:

appi.ps.201700439 (psychiatryonline.org)

65.9% misdiagnosis rate for depression in primary care:

Rates of Detection of Mood and Anxiety Disorders in Primary Care: A Descriptive, Cross-Sectional Study | Request PDF (researchgate.net)

Over 60M suffer from poor sleep quality and over 40M meet diagnostic criteria for sleep disorders:

Sleep Study | Johns Hopkins Medicine

Standardized PHQ-9 screening tool – incumbent for 20 years with no innovation:

https://www.medicalrepublic.com.au/strange-history-of-a-depression-screening-tool/86457

PHQ-9 overestimates the prevalence of depression:

https://www.sciencedirect.com/science/article/abs/pii/S0895435619307358#:~:text=PHQ%2D9%20%E2%89%A510%20substantially,correct%20statistically%20in%20individual%20studies.

PHQ-9 leads to over-prescription of anti-depressants:

https://www.medscape.com/viewarticle/831505?form=fpf

75% of people with Depression have trouble falling or staying asleep:

https://pubmed.ncbi.nlm.nih.gov/36644846/