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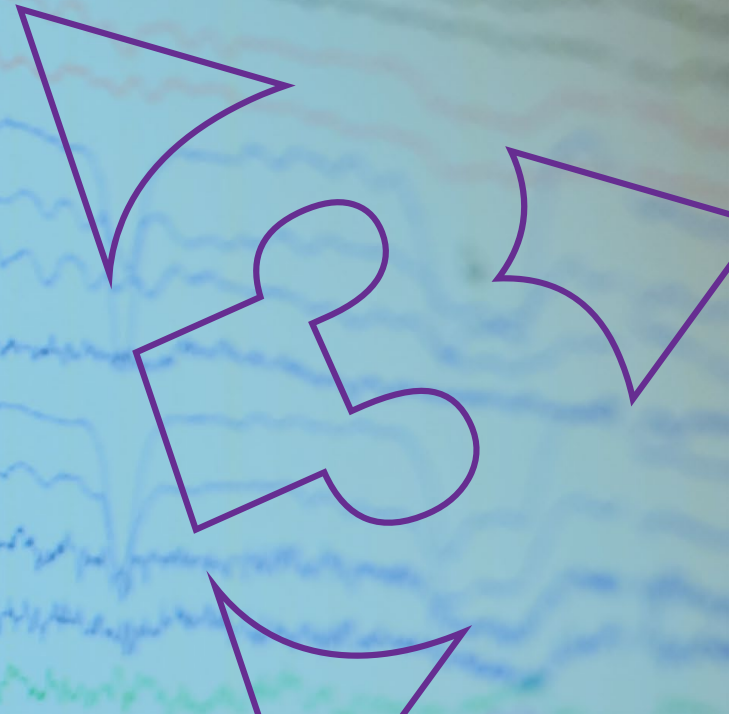


**Commercialising AI-driven solutions to  
objectively screen for mental health conditions**

**November 2023**

**(ASX: TRI)**

Authorised for release by the Board of TrivarX Limited



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# A US-based medical technology company

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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



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## US sleep clinic market growth:

**+ US\$15.92Bn**

Market value by 2028 at a CAGR of 8.2%

## Sleep disorders in the US:

**60m** people suffer from poor sleep quality

**40m** meeting diagnostic criteria for sleep disorder diagnosis

## Correlation between depression and sleep disorders:

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

## 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 not part of clinical practice in sleep clinics

## 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

## 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

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Integrated Care Model

## Stager

- AI-based software solution that provides researchers with new data metrics in sleep studies
- 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)

## MEB-001

- 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



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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



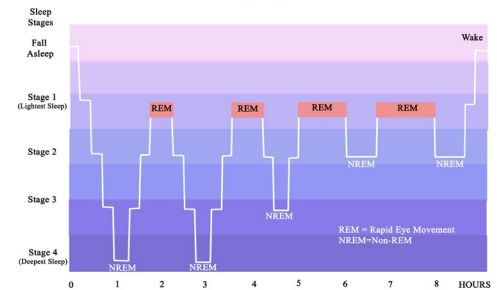
Solution provides information not available elsewhere with similar accuracy to human raters



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



Sleep Cycles



# Stager's unique features and benefits

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## 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

## Accuracy:



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

## Unique features and benefits:

### Feature:

Provides standard measures of HRV for each of the test subject's sleep stages

### Benefit:

Alternations in HRV are associated with autonomic dysregulation

### Feature:

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

### 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

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



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



Preliminary SAMDE Phase 1 clinical trial results taken from 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

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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 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

# 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:

**72%**

**Sensitivity**

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

**71%**

**Specificity**

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

**91%**

**Negative predictive value**

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%\*

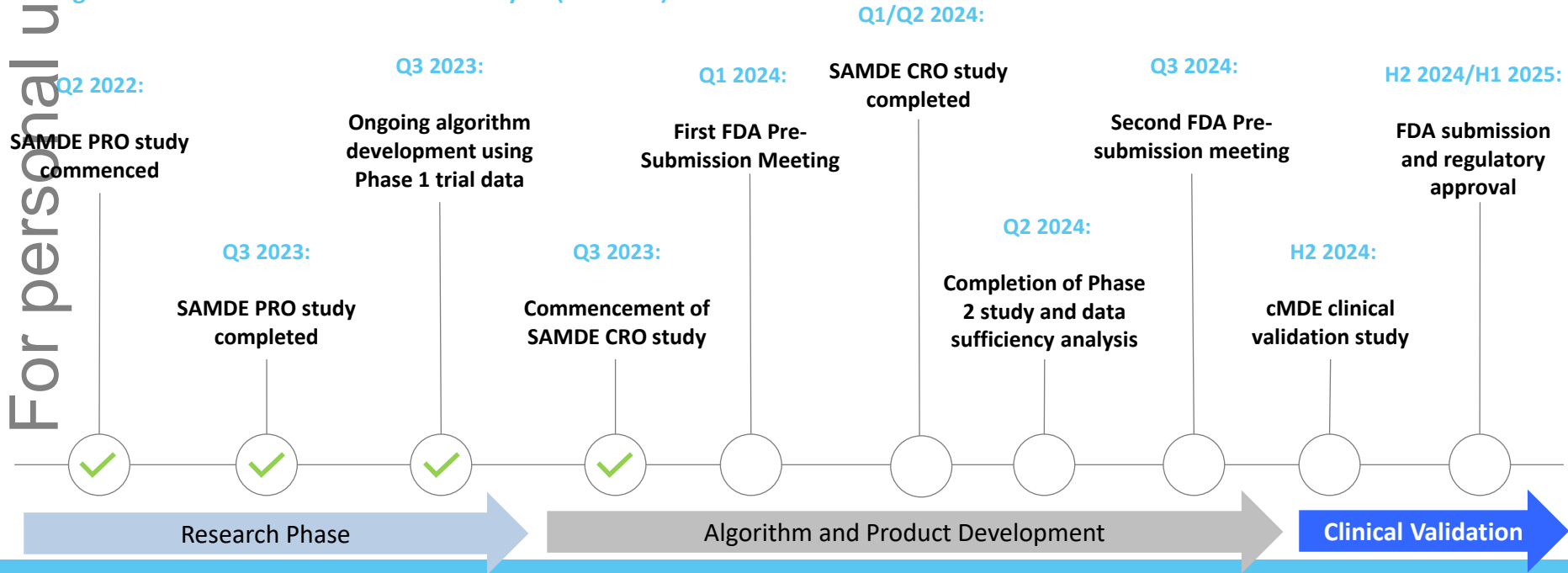
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# Phase 2 SAMDE trial underway



- 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):



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# Commercial adoption strategies for MEB's solutions



## Licensing 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

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Integrated Care Model

# Investment summary

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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



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

# Contact

**TrivarX Limited (ASX: TRI)**

**E:** [Investors@trivarx.com](mailto:Investors@trivarx.com)

**A:** 647 Beaufort Street, Mt Lawley, WA 6050

**Henry Jordan – Six Degrees Investor Relations**

**T:** +61 431 271 538

**E:** [Henry.Jordan@sdir.com.au](mailto:Henry.Jordan@sdir.com.au)

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# Appendix 1: Corporate overview



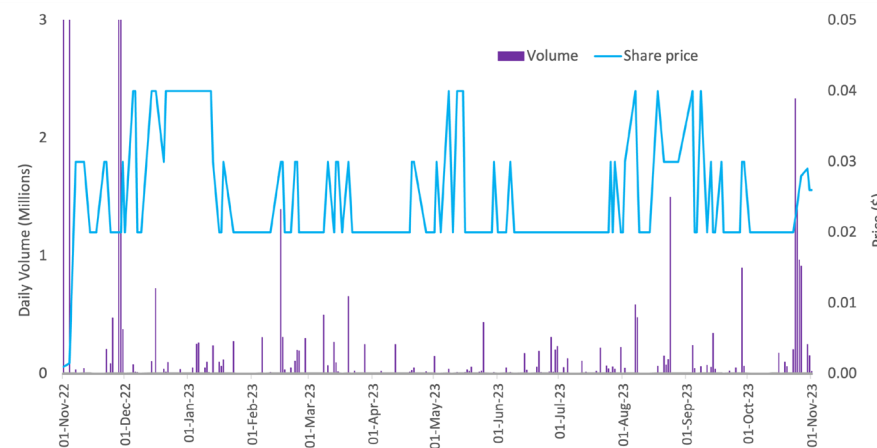
## Corporate snapshot

ASX code:	TRI
Shares on issue:	~335.7m
Market capitalisation (at \$0.03 per share): <small>(as at 9 November 2023)</small>	~\$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)



## Major shareholders

FIL Investment Management (Hong Kong) Limited	9.77%
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**Top 20: 55.94%**

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

# Appendix 2: Intellectual Property and patents



Four patents granted and currently active

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

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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.

4

**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, Connexions, 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

### Massimiliano Grassi – Head of AI

- 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

# 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](http://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/>

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