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Driving Better Outcomes

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

Investor Presentation – May 2023

(ASX: MEB)

Approved for release by the Board of Medibio Limited

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A US-based healthcare technology company

Integrated Care Model

- Commercialising **AI-driven**, **scientifically proven screening products** and **diagnostic tools** to assist in the screening and long-term monitoring of mental health conditions
- Focused on **whole person care** by integrating treatment for **physical health**, **mental health** and **sleep health**
- Two solutions for a **more cost-effective approach to screening** with **better patient outcomes** benefiting insurers, hospitals and GPs
- **Stager sleep software product** aimed at sleep research organisations in the US to **roll-out in coming months** – **targeting a US$9.2Bn market sleep medicine market**
- **MEB-001** – A **medical device to screen sleep study patients for the likelihood of a current major depressive episode** (cMDE). In **clinical development with plans for market authorisation via the FDA's De Novo pathway**
- Growth trajectory to be underpinned by **new Board and management** which includes **US-based mental health, sleep and healthcare professionals**

Corporate overview

Corporate snapshot	
ASX code:	MEB
Shares on issue:	4.15Bn
Market capitalisation (at $0.001 per share):	~$4.15m
Options on issue:	1.54Bn
Cash at bank:	~$1.81m
Debt:	Nil
52 week high – low:	$0.001 - $0.004

Major shareholders	
FIL Limited and ITS Associated Entities	9.99%
Rookharp Capital Pty Ltd	5.89%
Remaining top 20	**23%**

Share price and volume (May 2022 – May 2023)

Board and management	
Non-Executive Chairman	Mr David Trimboli
Chief Executive Officer	Dr Thomas Young
Non-Executive Director	Mr Chris Ntoumenopoulos
Chief Medical Officer	Dr Archie Defillo
Head of Artificial Intelligence	Mr Massimiliano Grassi
Chief Marketing Officer	Mr Dave Danielson
Company Secretary	Mr Stephen Buckley

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 – Chief Executive Officer

- 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 neuroscientist
- 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 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

CEO Profile - Dr Tom Young

A Board-Certified family physician, Dr Young brings over **45 years of medical experience in the US health sector**. With a successful career spanning public health policy, medical technology and entrepreneurship, Dr Young **is recognised in the US healthcare sector as an industry leader in consumer-directed healthcare and population healthcare management**.

In 2016, Dr Young **founded Nview Health** (now Proem Behavioral Health), a **leading behavioral health software engine**. **Proem is the exclusive digital licensee worldwide of gold-standard, evidence-based screening solutions, structured interviews, and post-diagnosis severity measurement scales to monitor patient outcomes for mental health**. Dr Young continues to serve as a board member, Chief Medical Officer and strategic advisor at the company.

Dr Young has also held **senior leadership roles at several large medical technology companies**, including:

- Executive Vice President and **Chief Medical Officer at Connextions, a leading US healthcare consumer engagement platform with ~8,000 staff that was acquired by NYSE-listed United Health Group** (NYSE:UNH)
- President at Behavioral Imaging Solutions, a leading med-tech globally recognised for its application of video imaging for the treatment of children with autism. He continues to serve in an advisory position at the Company.

Dr Young has also **remained active in health policy and higher education in his home state of Idaho**, where he continues to practice as the medical director for the College of Idaho and a local substance abuse treatment facility. His past experience also includes six years as Medical Director of Idaho Medicaid, and nine years as Chief Clinical / Medical Officer of Idaho Medicare.

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 <u>not</u> 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 Medibio solution:

Clinically validated solutions measuring biometric data, brain and heart functions to identify mental health conditions and deliver better, cheaper patient care

Taking mental health diagnosis from subjective to objective 2

Defined solutions offering

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 (current gold standard)

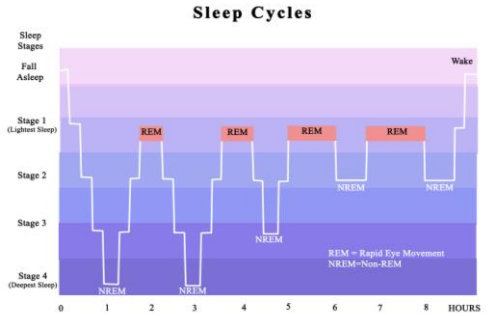
MEB-001

- A medical device to screen sleep study patients for the likelihood of current major depressive episode.
- Uses Biometric Data, EEG (Brain), ECG (Heart Rate) and HRV (Heart Rate Variability) scans collected during-in-clinic sleep studies
- In clinical development, with plans for market authorization via the FDA's De Novo path

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 with commercial roll out expected H2 CY2023
- 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



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:	Benefit:
Provides standard measures of HRV for each of the test subject's sleep stages	Alternations in HRV are associated with autonomic dysregulation
Closer alignment with human raters for N3 Stage and REM sleep stages, which are key indicators of mental health	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 for Current Major Depressive Episode using objective data from in-clinic sleep studies

There is only a 1.4% depression screening rate for all adult outpatient care visits in the US. MEB-001 aims to provide a standardised solution for effective depression screening

Clinical validation will compare MEB-001 against ground truth for the presence of current major depressive episode in accordance with FDA requirements

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

Sleep Signal for Current Major Depressive Episode trial

- Sleep Analysis of Depressive Burden Study (SAMDE) - Phase 1 trial commenced in July CY2022 with results to be used to re-train MEB-001 algorithm based on information collected from additional primary endpoint (MINI)
- Data collected from trial patients that self-report answers as part of their Mini International Neuropsychiatric Interview (MINI) assessment
- Trial currently involves 12 sleep centers across the US in 5 states with 319 patients recruited to date
- MINI data to test MEB-001 algorithm performance for sensitivity, specificity and negative/positive predictive values
- Aim of the trial is to validate MEB-001's capacity to screen the likelihood of a current major depressive episode in individuals referred to sleep clinics for polysomnography assessment

Progress to date:

March CY2023:

Lodgement of SAMDE study (MEB-001) algorithm under Breakthrough Device Designation with FDA

Phase I of trial ended with 319 subjects enrolled

Ongoing algorithm development with early data highlighting better accuracy that current Standard of Care

May CY2023:

Phase II of trial commencing with clinicians reporting output of MINI assessment via interactive interview

Expected to require ~250 patients with additional 3-5 sleep centres

Trial expected to complete in 20 weeks of commencement

Next steps: CY2023:

FDA Pre-Submission Meeting expected to occur in October 2023

Beginning of Clinical Validation - March CY2024

MEB-001 De Novo Submission to FDA - September CY2024

Ongoing algorithm development

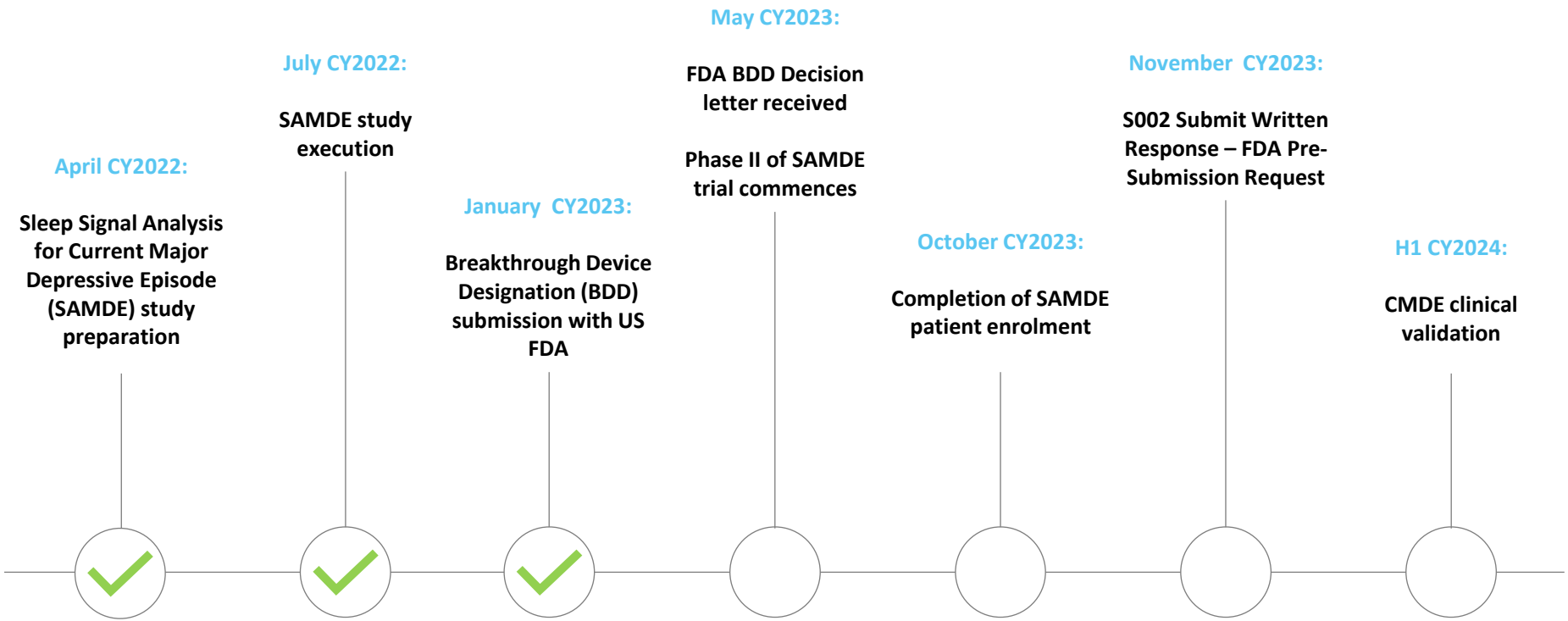
- MEB''s clinical team has continued to enhance the MEB-001 algorithm development and focus on cross-centre performance stability, as well as increase results repeatability, internal consistency and improve accuracy

Early test results for accuracy highlight:

72%	71%	91%
Sensitivity	**Specificity**	**Negative predictive value**
The ability for the test to correctly identify patients with the disease	**The ability to designate and individual who does not have the disease as negative**	**The likelihood that an individual with a negative test result does not have the disease, condition of relevant biomarker**

Early training data has exceeded the accuracy for the current Standard of Care screening in sleep centers

Work to date has led to a defined FDA pathway



Commercialisation pathway will be coupled with ongoing R&D and product development initiatives for MEB-001

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

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 and established regulatory route

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

Considerable potential to expand clinical offerings and functionality of Stager and MEB-001 products through AI and machine learning technology

Commercial roll-out of Stager underway with licensing agreements and partnerships anticipated H2 CY2023 – providing near term revenue opportunities

Additional studies ongoing to materialize future product development

Underpinned by a Board and management team with unparalleled success in the US and global healthcare markets

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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.