# medibio

**Investor Update** 

May 2019

LOOKING AT MENTAL HEALTH, OBJECTIVELY

# **Forward Looking Statements**

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# medibio

The mental health technology company leveraging objective digital biomarkers for products and services that assist in screening, diagnosing, monitoring, and managing of depression and other mental health conditions.

# **Corporate Structure**

CAPITAL STRUCTURE (ASX:MEB) (OTCQB:MDBIF)

Market Cap	AU\$4.05M
Share price as of 05 May 2019	AU\$0.012
Shares on Issue	249M
Shares of convertible notes <sup>1</sup>	138M
Cash <sup>1</sup>	AU\$2.9M

# Shortfall

Shares Available	156.5M
Shares on Issue*	543.5M

<sup>1.</sup> Convertible notes have mandatory conversion June 2021

<sup>2.</sup> Cash balance as of 31 March 2019

<sup>\*</sup> Assumes full uptake on shortfall and conversion of notes

# **Re-Startup Strategy**

Medibio's RE-STARTUP is progressing on plan:

- √ Restructured Board and Key Management
- ✓ New Cost Controls to Reduce Cash Burn
- √ Strengthened Regulatory Path
- √ Commercial launch of ilumen<sup>TM</sup>



# **Board** of Directors



**DAVID B. KAYSEN**Chair, Managing Director & CEO



PETER CARLISLE
Lead Independent Director
Managing Director, Olympics &
Action Sports, Octagon Worldwide



DR FRANKLYN G PRENDERGAST
PhD MD, Non Executive Board Member
Former member board of Trustee and Board of
Governors Mayo Clinic and board member Eli Lilly



PATRICK KENNEDY
Non Executive Director
Former US Congressman
Founder, Kennedy Forum



MICHAEL PHELPS
Non Executive Director
Mental Health Advocate



CLAUDE SOLITARIO

Non Executive Director
Founding Shareholder

6



MELANIE LEYDIN

Director & Joint Company Secretary
B. Bus, CA



MATHEW WATKINS

Joint Company Secretary

B. Bus, CA

#### **Executive Team**



**DAVID B. KAYSEN**Chair, Managing Director & CEO



PEGGY MORGAN
Corporate Controller



ARCHIE DEFILLO
Chief Medical Officer



JEREMY SCHROETTER
Chief Technology Officer



JENNIFER SOLITARIO
Senior Vice President Corporate Health



**LINDSEY HAGAN**Vice President Strategy & Business
Development

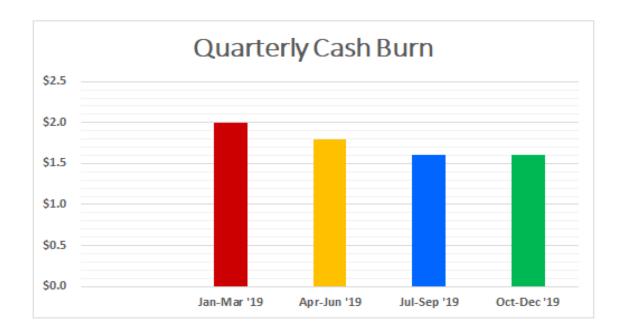
#### **Cost Controls to Reduce Cash Burn**

# Focus on reducing cash burn:

- Significant reduction in force, U.S. office
- Cash compensation eliminated for NED's, effective 1 January 2019
- All line item spending scrutinised & reduced
- Reduction in spending in Australian office
- Outsourcing of psychology services in support of ilumen<sup>TM</sup> corporate health product
- Downsized Perth premise and working to sublet or reassign the current lease on the property



# **Quarterly Cash Burn**



- January March represents actuals.
- Subsequent quarters represent projected cash burn.

# **Business Objectives – Regulated & Unregulated Product Pipeline**

# Next 6 - 9 months

#### **CE Mark Opportunities**

# U.S. FDA Regulated Products

# Global ilumen™ Expansion

# Longer Term Objectives

Future Commercialisation Efforts

- Leverage recent ISO13485 re-certification with expanded scope
- Finalize a revised CE Mark product no later than September 2019
- Define commercialisation opportunities in the European Union
  - Build strategic alliances/partnerships with Clinical Research Organisations (CRO), European Sleep Study Societies, and pharmaceutical companies
- Engaged DuVal & Associates as FDA Counsel
- Identified long-term FDA strategy
- Filing new De Novo in late 2019
- Provide clinicians ability to better assess patient's mental health
  - Use of data from sleep studies
- With success of pilots, will move to annual subscription-based pricing model
- Work to integrate ilumen™ into organisations with global distribution channels
- Seek to generate revenue through annual license fees and royalties based on usage
- Leverage U.S., Australian and European relationships clinical partners, universities/hospitals, Scientific Advisory Board
- U.S. FDA decision on new De Novo submission expected late 2020

# **Product Overview – U.S. Regulated Pathway**

# **FDA De Novo**









Clearance

**Go to Market** 

- De Novo to be filed in late 2019
- Improve Clinician assessment of patient's mental health
- Continue to prepare new FDA De Novo Application
  - Company has begun positive and open dialogue with FDA
  - FDA is helping to guide us through the process and has provided excellent directional feedback about our technology
  - Company is encouraged by dialogue with FDA, with end point anticipated in late CY2020

# U.S. Sleep Studies Market Data

 In 2015, 2,800 labs had an estimated \$7.1 billion in revenue. By 2020, the industry will be within the \$10 billion mark.<sup>1</sup>

- Average of 7.7 beds in each center<sup>2</sup>
- 5 nights a week
- ~ 4.4 million studies each year\*

 A mild sleep apnea sufferer is twice as likely to have depression.<sup>3</sup>

<sup>1. &</sup>lt;a href="https://www.forbes.com/sites/daviddisalvo/2015/08/06/how-the-sleep-industry-is-making-billions-from-your-lack-of-shuteye/#349d60cf2542">https://www.forbes.com/sites/daviddisalvo/2015/08/06/how-the-sleep-industry-is-making-billions-from-your-lack-of-shuteye/#349d60cf2542</a>

<sup>2.</sup> http://www.sleepreviewmag.com/2016/05/first-quarter-2016-sleep-center-survey-results/

<sup>3. &</sup>lt;a href="https://www.novasom.com/for-patients/sleep-apnea-related-conditions/depression/">https://www.novasom.com/for-patients/sleep-apnea-related-conditions/depression/</a>

<sup>\*</sup> Assumes 80% utilisatio

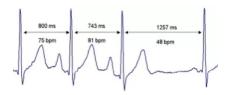
# **Potential Commercialisation & Partnership Opportunities**

Company	Focus	Organization Revenue	Opportunity
Philips Respironics USA	Sleep and Respiratory Care	\$1.1B	Licensing, royalty fee per usage
ResMed Inc. USA	Sleep apnea, COPD, and other chronic diseases	\$2.3B	Licensing, royalty fee per usage
Natus Medical, Inc. USA	Polysomnography Software	\$500M	Licensing, royalty fee per usage
Compumedics, Ltd. Australia, China, Japan	Sleep Diagnostics	\$34.4M	Licensing, royalty fee per usage

# U.S. FDA Path - New De Novo

# **Types**

#### **Cardiac**





Heart Rate Variability

Circadian

# Brain

# **Pulmonary**





Electroencephologram



Respiration

# Sources

# **Polysomnography**



Lab and In-home Studies

# Wearables



# Quality

# Laboratory



Sleep Centers

### **Environment**





Calm

Sleep

## U.S. FDA Path – Indication of Use – New De Novo

Depressive burden is the cumulative load of depressive symptoms upon an individual.

The Beck Depression Inventory (BDI-II) is a measure of the severity of depression symptoms during a depressive episode. This is a subjective measure of depressive burden.

The use of the BDI-II is prevalent in many practices for the screening of depression, as well as polysomnography studies.

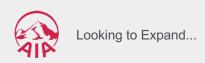
# **Product Overview - Corporate Health**

#### **Australia**

ilumen™ in Corporate Health Market



- Pilot programs marketed to large corporations with goal to scale up partnerships
- One pilot completed with high participation
- AIAA pilot commences in March 2019
- In discussion with large multinational company with potential for several pilot programs
- Receiving unsolicited enquiries from large corporations AUS + U.S.
- Being selective due to constraints with funding and people, while focusing on large scale commercialisation
- App based system provides feedback to individual
  - De-identified aggregate feedback to Corporate partner



- Focus on Better Use of Biometrics
- Continue to Improve Biometric Algorithm (based on wearable data collected)



# **Recent Capital Raising**

- Completed Convertible Note issue in January 2019, raising approximately \$2.75 million over two tranches
- Completed a Non-Renounceable Entitlement Offer to existing shareholders raising \$923,465
- The Company is seeking to fulfil the shortfall on the Entitlement issues, which will provide a longer-term runway
  - Approximately 150M shares at \$0.02 AUS = \$3.1M
- The combined capital raisings, based on strong participation on the shortfall, is expected to provide 12+ months of cash with cost reductions in place

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#### **THANK YOU**

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