



medibio

# 2020 AGM PRESENTATION

ASX: MEB  
OTCPINK: MDBIF

NOV 2020

## FORWARD LOOKING STATEMENTS

# FORWARD LOOKING STATEMENTS

The purpose of the presentation is to provide an update of the business of Medibio Limited (ASX:MEB) (OTCPINK: MDBIF). These slides have been prepared as a presentation aid only and the information they contain may require further explanation and/or clarification.

---

Accordingly, these slides and the information they contain should be read in conjunction with past and future announcements made by Medibio Limited and should not be relied upon as an independent source of information. Please contact Medibio Limited and/or refer to the Company's website for further information. The views expressed in this presentation contain information derived from publicly available sources that have not been independently verified.

None of Medibio Limited, or any of its affiliates or associated companies (or any of their officers, employees, contractors or agents (the Relevant Persons)) makes any representation or warranty as to the accuracy, completeness or reliability of the information, or the likelihood of fulfilment of any forward looking statement or any outcomes expressed or implied in any forward looking statements.

Any forward looking statements in this presentation have been prepared on the basis of a number of assumptions which may prove incorrect and the current intentions, plans, expectations and beliefs about future events are subject to risks,

uncertainties and other factors, many of which are outside Medibio Limited's control. Important factors that could cause actual results to differ materially from assumptions or expectations expressed or implied in this presentation include known and unknown risks.

Because actual results could differ materially to assumptions made and Medibio Limited's current intentions, plans, expectations and beliefs about the future, you are urged to view all forward looking statements contained in this presentation with caution. Except as required by applicable law or the ASX listing rules, the Relevant Persons disclaim any obligation or undertaking to publicly update any statements in this presentation, whether as a result of new information or future events.

***This presentation should not be relied on as a recommendation or forecast by Medibio Limited. Nothing in this presentation constitutes investment advice or should be construed as either an offer to sell or a solicitation of an offer to buy or sell shares in any jurisdiction.***



## LOOKING AT MENTAL HEALTH OBJECTIVELY

A mental health technology company pioneering the use of objective measures to aid in the **early detection** and **screening** of **mental health** conditions.

Pioneering the use of objective measures with artificial Intelligence and neural network methodology to aid in the early detection and screening of mental health conditions



*"We will no longer endorse DSM5, as it has fundamental flaws and we are actively seeking a diagnostic system that is evidence based. We need a quantitative method for diagnosing depression"*

*- National Institute of Mental Health in the USA, 2013*

# DEPRESSIVE BURDEN TRIAL (SADB) TO VALIDATE MEB- 001

MEB-001 is a software medical device that consists of 3 main components:

1 The sleep staging algorithms; overlaid by

2 Resting heart rate and heart rate variability algorithms, that will lead to:

3 The Depressive Burden Analysis

Our team in Minneapolis is currently undertaking a clinical trial known as the

“Sleep Analysis of Depressive Burden”

The purpose of the trial is to clinically validate MEB-001 as a medical device.

MEB-001 aims to provide the clinician with an objective, data-driven approach, to assist in the diagnosis of depression, based on the patient’s own biological data.

## BREAKTHROUGH DEVICE DESIGNATION- FOR MEB - 001

To qualify for Breakthrough Device Designation we must establish that MEB-001 promises a more effective diagnosis of a life-threatening or irreversibly debilitating condition; and meet at least one of the following criteria:

- a) That MEB-001 represents breakthrough technology;
- b) There are no approved or cleared alternatives;
- c) That MEB-001 offers significant advantages over existing approved or cleared alternatives; or
- d) That MEB-001's availability is in the best interest of patients.

The benefits of Breakthrough Device Designation are that it will

**A**

fast-track the FDA's review process; and

**B**

provide us with additional opportunities to interact with FDA senior management.

---

The FDA has advised that they will provide a final decision to grant or deny our request within 60 calendar days. We estimate this to be around 30th November 2020.



## MEBSleep

MEBSleep uses artificial intelligence, deep learning algorithms and neural network methodology to identify the five important sleep stages of a patient.

The primary purpose of MEBSleep is the identification of sleep stages, which is an essential part of MEB -001.



**MEBSleep is able to identify the sleep stages in 2 minutes, what would normally take a clinician, anywhere between 1 and 2 hours**



**It is this characteristic that inspired our regulatory team to apply for a 510(k) clearance for MEBSleep, opening up the possibility of generating early revenue**



**The 510(k) application was submitted on the 29th April. On the 24th August, we received notification from the FDA that our application was found to contain all the necessary elements and information needed to proceed with a substantive review**

## MEB-001 / MEBsleep REVENUE MODEL

**Medibio will earn revenue based on the number of depressive burden and/or sleep staging reports produced**





## CLINICAL TRIAL AGREEMENT WITH MEDBRIDGE HEALTHCARE LLC IN THE USA

As we have previously reported, the closure of sleep clinics in Minneapolis due to the COVID-19 lockdown put a sudden stop to our depressive burden trial for a period of approximately 3 months.

In order to make up for lost time, on 24 August, we were delighted to sign a Clinical Trial Agreement with MedBridge Healthcare LLC in the USA.

MedBridge is the leading provider of sleep laboratory management services in the United States, operating over 130 sleep disorder diagnostic centres.



*“The objective identification of depression in patients that suffer certain sleep disorders is an unmet need and we are pleased to be working with Medibio to fast-track patient recruitment for the SADB trial.”*

*“As the leading sleep management service provider in the US, we are excited about the potential of Medibio’s technology and its clinical applications” - Mr John Mathias, Chief Development Officer of MedBridge*

# BENEFITS of ILUMEN



## FOR EMPLOYERS

Provides employers with a realtime, de-identified, aggregated dashboard of their workforce's results to better support and manage the mental well-being of its workforce and measure the impact of their programs



## FOR EMPLOYEES

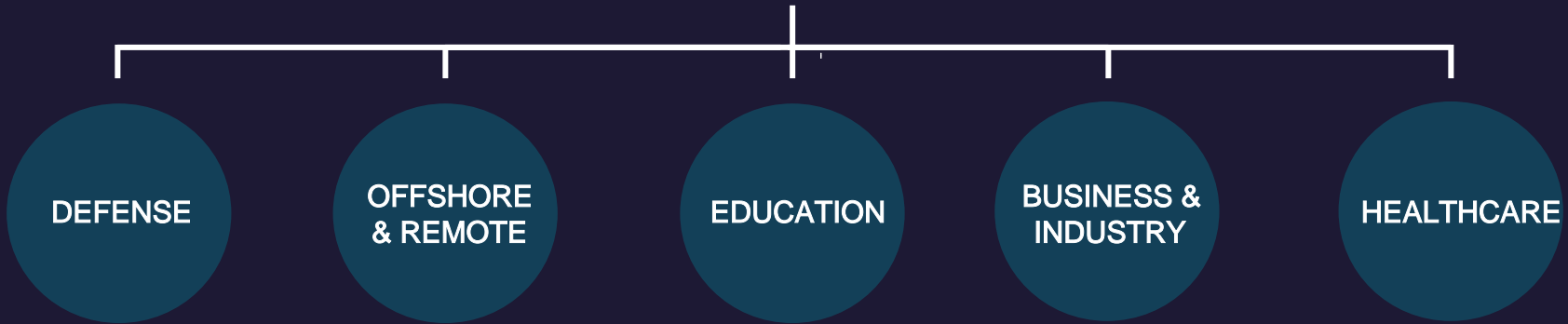
Provides employees an early screening tool for symptoms of stress and a 'wellbeing snapshot' they can use to make improvements over time



# COMPASS GROUP PLC



GLOBAL (600,000 employees, 45 countries)



Mr Federico Tonetti,  
Global Safety & Sustainability Director at Compass in London.

“When dealing with mental health, the biggest challenge as an employer is moving the emphasis from the input of what we do, to measuring the output. There are many campaigns around mental health. Many countries have mental health month, many countries have established a hotline to help people, many countries have established internet portals to assist one's mental health. This is what we are putting into the system and hoping to have a positive impact on mental health. The challenge for us is measuring the output. By that I mean: How many people can we effectively save from mental health issues? Is the percentage of high risk employees going down or not? Is the number of productive hours going up or down? I believe that if we are serious about mental health, we must measure the impact of what we do; and **I haven't found so far, any better product than ilumen to do this”.**

# REVENUE MODEL- SasS MODEL, ENTERPRISE LICENSE (\$ Per Employee, Per Annum)



# CONSUMER APP





## LOOKING FORWARD/ 2020 -2021

We look forward with a great deal of confidence to achieving a number of significant milestones.

Securing the first of many Compass Companies and Compass client companies for ilumen globally;



Securing additional ilumen licenses in Australia as borders reopen;



510(k) clearance for MEBsleep paving the way for potential early revenue of a regulated product;



Securing Breakthrough Device Designation;



Pre-submission meeting with the FDA to agree on endpoints for our depressive burden trial;



Commercial launch of our Consumer App; and



Completing the depressive burden trial for the De Novo application for MEB -001 in 2021, to which we can then lay claim to having developed the world's first objective test for depression





medibio

**CLAUDE SOLITARIO**  
Managing Director

**Melbourne**  
Level 4, 100 Albert Road  
South Melbourne VIC  
3205

**United States HQ**  
8696 Eagle Creek Circle  
Savage, MN 55378