# medibio

## Investor Presentation

December 2018

**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.

# Medibio Update

New
Focus

Clear
Direction

New Path
Forward

**Path to
Commercialisation**
CY 2019

# New Focus

▶ Eliminating Distractions as Quickly as Possible

▶ Challenge All Spending to Conserve Cash

▶ Prioritize Business Segments

▶ Strengthen Regulatory Path

▶ Open & Honest Communication to All

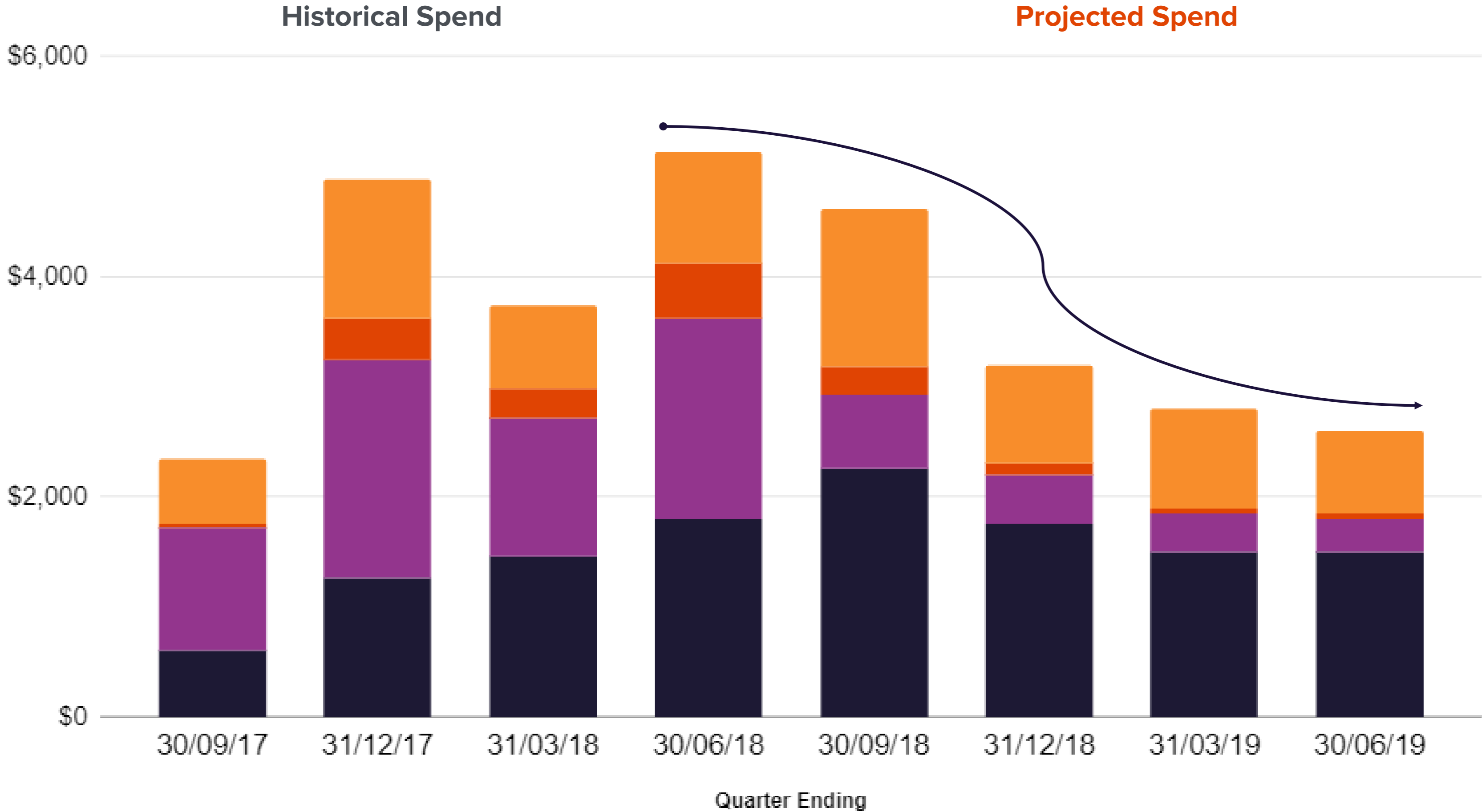# New Path Forward

▶ Right-Size the Business

▶ Ruthlessly Challenge All Spending

▶ Strengthen Regulatory Path

▶ Commercialisation in 2019

Quarterly Cash Burn - Fiscal Years 2018 & 2019

# Corporate Structure

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

| | |
|---|---|
| **Market Cap** | **AU$7.7M** |
| Share price *as of 26 November 2018* | AU$0.038 |
| Shares on Issue | 203M |
| **Cash[1]** | **AU$3.5M** |

1. Cash balance as of 31 October 2018.
2. Percentages based on available information, including share registry, options listing, ASX filings, and other reported data
3. Includes shares on issue and vested board & management options

### Significant Institutional Investors

**Fidelity**                    **9.1%**

Fidelity

**REGAL FUNDS MANAGEMENT**       **7.0%**

Regal Funds Management
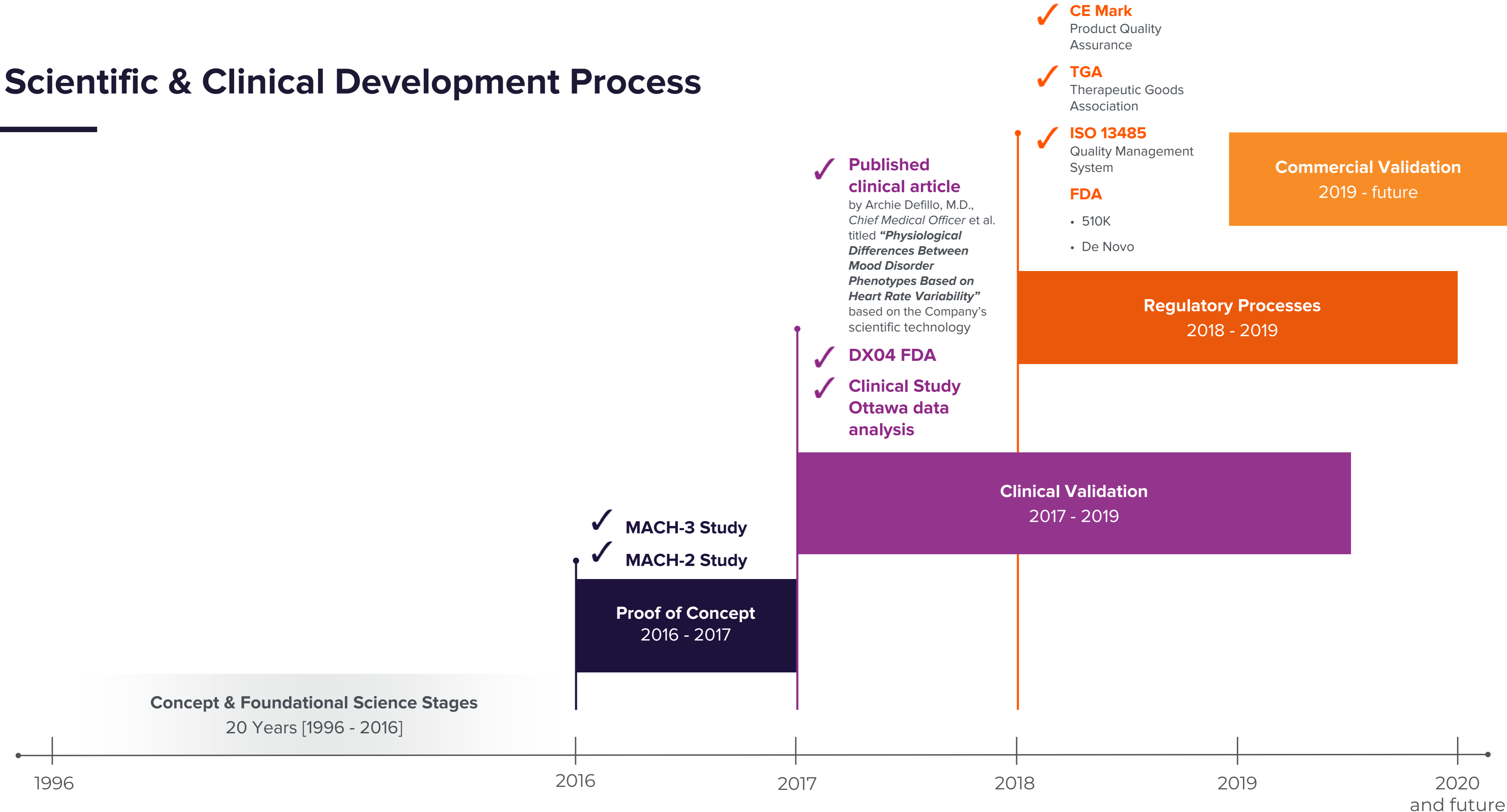
### Shareholder Mix[2, 3]

| | |
|---|---|
| Private Holders | **57.2%** |
| Institutional Holders | **40.1%** |
| Board and Management | **2.7%** |

# Scientific & Clinical Development Process

✓ **CE Mark**
Product Quality
Assurance

✓ **TGA**
Therapeutic Goods
Association

✓ **ISO 13485**
Quality Management
System

**FDA**
- 510K
- De Novo

**Commercial Validation**
2019 - future

✓ **Published clinical article**
by Archie Defillo, M.D.,
*Chief Medical Officer* et al.
titled **"Physiological Differences Between Mood Disorder Phenotypes Based on Heart Rate Variability"**
based on the Company's scientific technology

✓ **DX04 FDA**

✓ **Clinical Study Ottawa data analysis**

**Regulatory Processes**
2018 - 2019

**Clinical Validation**
2017 - 2019

✓ **MACH-3 Study**

✓ **MACH-2 Study**

**Proof of Concept**
2016 - 2017

**Concept & Foundational Science Stages**
20 Years [1996 - 2016]

1996      2016      2017      2018      2019      2020
and future
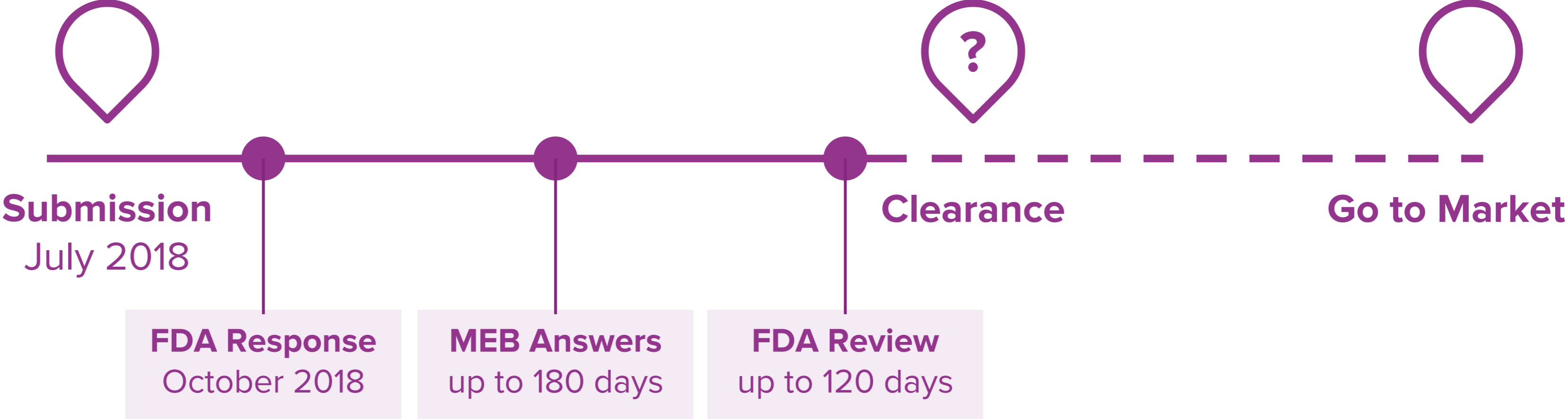
# Regulatory Validation & Publications



510K path
De Novo path

Mayo Clinic
Convergence
Neuroscience
2018 Course

# U.S. Regulatory Path to Commercialisation

**FDA 510k Clearance**
Class I or II Device

Submission ———————————— Clearance - - - - - - - - - Go to Market

▷ Use a "Predicate" Technology

▷ Technology Must Be Low-risk

▷ Typically 90 Days to Clearance

▷ Vast Majority of Medical Devices/ Technology

# U.S. Regulatory Path to Commercialisation

**FDA De Novo Clearance**
Class I or II Device

**Submission**
July 2018

**Clearance**

**Go to Market**

**FDA Response**
October 2018

**MEB Answers**
up to 180 days

**FDA Review**
up to 120 days

▶ New Technology or
New Indication for Use

▶ Unknowns
- Timeline for FDA Questions
- Timeline for Sponsor Replies

▶ Process Depends on
Back and Forth

▶ Often Requires Study with Submission

▶ FDA Evaluates Safety and Efficacy

▶ Ongoing Interaction is Positive

# Commercial Opportunities

## Australia
Ilumen in Corporate
Health Market



Looking to Expand...

Small Start with Pilots

Need to Refine the Business Model

Provide Better Feedback

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

Develop IP in This Space

Refine Pricing Model for Revenue

Improve Partnership and Integration Opportunities

Manage Our Costs

# Commercial Opportunities

**USA**
with Regulatory
Clearance

▶ Two Paths:

 **De Novo**

**No Specific Timeline**

 **501K Clearance**

- **1 or more applications**
- **Expect clearance by 2019**
- **Lead to commercialisation in 2019**

▶ Focus Will Be on Medical - Integrated Health Solutions

▶ Will evaluate Corporate Health

▶ Consumer in the Future

# Board of Directors

**CHRIS INDERMAUR**
Chairman
B. Eng. (Mech.), Grad Dip Eng. (Chem.), LLB,
LLM, Grad Dip LP

**PETER CARLISLE**
Vice Chairman
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

**ANDREW MAXWELL**
Non Executive Director
MBA, MAcc, ACPA

**DAVID KAYSEN**
CEO & Managing Director

**MELANIE LEYDIN**
Company Secretary
B. Bus. (UTS), Grad. Dip. DP (UTS), CA, AGIA

# Executive Team

**DAVID KAYSEN**
Chief Executive Officer

**BRIAN MOWER**
CFO
B.S., MAcc, CPA

**ARCHIE DEFILLO**
Chief Medical Officer

**JEREMY SCHROETTER**
Chief Technology Officer

**LINDSEY HAGAN**
Vice President Integrated Health

**JENNIFER SOLITARIO**
Senior Vice President Corporate Health

**PATRICK MIDDEN**
Chief Privacy Officer

# SCIENTIFIC ADVISORY BOARD

## External Advisors:

### Martin Chapman, MBBS FRANZCP
Psychiatrist and Fellow of the **Royal Australian and New Zealand College of Psychiatrists**. As a medical administrator he has worked in both hospital and community settings in private and government sectors. His clinical practice is in the area of treatment resistant mood and anxiety disorders. He has taught in undergraduate and postgraduate Psychiatry with a focus in assisting primary care physicians in their management of mental health conditions. He has an interest in mental health system development and the role of new technologies in streamlining and providing clinical decision support.

### Joel R. Ehrenkranz, M.D.
Endocrinologist on the faculty of the **University of Colorado School of Medicine** and a biotech entrepreneur in Salt Lake City, Utah. Dr. Ehrenkranz received his M.D. degree from Stanford and trained in internal medicine at Columbia University, neurology at Memorial Sloan Kettering Cancer Center, and endocrinology at the National Institutes of Health.

### Mark A. Frye, M.D.
Chair of the Department of Psychiatry and Psychology at **Mayo Clinic**. He also serves as director of the Mayo Clinic Depression Center. Dr. Frye received his M.D. from the University of Minnesota and completed his psychiatric training at the Semel Institute for Neuroscience and Human Behavior at the David Geffen School of Medicine at UCLA. He subsequently completed a fellowship at the National Institute of Mental Health in Bethesda, Maryland with a research focus on the neurobiology of treatment resistant depression and bipolar disorder.

### Lawrence Hunter, Ph.D.
Professor at the **University of Colorado** and directs the Computational Bioscience Program. He earned his degrees from Yale University, including B.A. in Psychology (cum laude); M.S. and M. Phil. and Ph.D. in Computer Science.

### Wallace Mendelson, M.D.
Psychiatrist and author, and was formerly **Professor of Psychiatry and Clinical Pharmacology**, and director of the **Sleep Research Laboratory**, at the **University of Chicago**. Dr. Mendelson earned an MD degree from Washington University School of Medicine in St. Louis and completed a residency in psychiatry there as well. He has held professorships at Ohio State University and the State University of New York at Stony Brook, was Chief of the Section on Sleep Studies at the National Institute of Mental Health in Bethesda, MD, and Director of the Sleep Disorders Center at the Cleveland Clinic.

### Marie Casey Olseth, M.D.
Currently in private practice as a Board Certified Adult Psychiatrist in the group practice that she owns. She earned her of Medicine degree from the University of Minnesota Medical School and completed her residency in General Psychiatry at the University of Minnesota and University of Wisconsin, Madison.

### Giampaolo Perna, M.D., Ph.D.
Currently Chair of the Department of Clinical Neurosciences at **San Benedetto Menni Hospital of the Hermanas Hospitalarias (Como Lake)** and Academic Coordinator of Mental Health and Adjunct Professor at **Humanitas University (Milan)**, in Italy. He earned his degree in Medicine and Surgery at the State University of Milan, followed by Ph.D. and completed a residency in Psychiatry there as well. He is the Chair of WPA section on personalized psychiatry and Co-editor in chief of the Elsevier Journal "Personalized Medicine in Psychiatry".

## Internal Advisors:

### Archie Defillo, M.D.
Currently the Chief Medical Officer at **Medibio Limited**. He has over 25 years of clinical experience with neurological diseases. For the past 13 years his efforts have been focused in neurological research. His research interests include cerebrovascular, stroke, neuro-trauma, brain oxygenation, metabolism and autonomic dysfunction. Based on his extensive academic work, in 2012, he was selected a scientific member of the Congress of Neurological Surgeons.

### Franklyn Prendergast, M.D., Ph.D.
Currently a director on the **Medibio Limited** board and chair of the Scientific Advisory Board. Previously, he was the Emeritus Edmond and Marion Guggenheim Professor of Biochemistry and Molecular Biology and Emeritus Professor of Molecular Pharmacology and Experimental Therapeutics, Mayo Medical School, to its Physician Advisory Board.

Dr. Prendergast earned his medical degree with honors from the University of West Indies. He attended Oxford University as a Rhodes Scholar, where he earned his masters degree in Physiology. After completing residency in Internal medicine at The Mayo Clinic in Rochester, Minnesota he earned a doctorate degree Biochemistry from the University of Minnesota/Mayo Graduate School.

Positions held: Chair, Department of Biochemistry and Molecular Biology; Director for Research Mayo Clinic (Rochester) (1989-1992). Board of Governors Mayo Clinic in Rochester; Mayo Clinic Board of Trustees (1992-2009); Mayo Clinic Board of Governors (1999-2006). Mayo Distinguished Investigator; Emeritus Director, Mayo Clinic Comprehensive Cancer Center and Mayo Center for Individualized Medicine.

In addition to his current role as a director on the Medibio board and chair of the Scientific Advisory Board, Dr. Prendergast holds numerous appointments with Industry and Extramural academic affiliations. He has extensive interactions over many years with National Institutes of Health (NIH): Board of Advisors for the Division of Research Grants; National Advisory General Medical Sciences Council; Board of Scientific Advisors of the National Cancer Institute; and the National Cancer Advisory Board.

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# Summary

**21 million suicide attempts from mental illness**
Of those, nearly 1 million are successful

**Biometric-based technology**
to identify, monitor and treat mental health conditions

**20+ years**
of scientific rigor

Ready to change the way the world looks at Mental Health,

**OBJECTIVELY.**

**Corporate Health**
**64 million** employees
**Consumer Health**
**266 million** lives
**Integrated Health**
**450 million** lives

THANK YOU

**David B. Kaysen**
CEO and Managing Director
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Savage . MN 55378 USA

# Appendix

# The Challenge

## IN ORGANISATIONS

Mental Health in the Workplace

Only **3.5%** of employees will utilize their employee assistance program, at an approximate cost of

**$2.1 MILLION**

**90%** of employees in severe ranges will go untreated

**2.9 MILLION** Hours per year of lost productivity

**20%** of employees meet the diagnostic criteria for depression

**2.30** Return on investment through early and effective targeted interventions

# The Challenge

## IN SOCIETY

Stigma and lack of access are prevalent globally

**21 million** suicide attempts from mental illness

Of those, nearly **1 million** are successful

In 2015, suicide was the **2ND** leading cause of death among 15 to 29 year-olds globally

**300 MILLION** suffer from depression

**1 in 13** suffer from anxiety

**7.7 MILLION** PTSD sufferers in the United States alone

# The Challenge

## IN THE HEALTHCARE SYSTEM

Only **1 psychiatrist per 100,000 people** in over half the countries in the world

**40%** of countries have less than one hospital bed reserved for mental disorders **per 10,000 people**

Out of **350 million** patients globally **< 7%** receive optimal treatment

**50%** are never diagnosed

**30%** are incorrectly diagnosed

**$94.5 BILLION** direct cost to treat Major Depressive Disorder (MDD) annually in the USA

**$12.6 BILLION** direct cost to treat depression annually in Australia

# The Science

## PIONEERING RESEARCH

Mental Illness and Biomarkers
in the Human Body

### Physiology

Our approach exploits features of
cardiovascular physiology influenced
directly by the autonomic nervous system
and susceptible to disruption during sleep,
as a source of biometrics that correlate with
onset and existence of mental dysfunction.

**20+ years of data collected**

### Data Science

Our approach focuses on using Artificial
Intelligence to monitor mental illness types
(such as depression, PTSD, anxiety and
stress) and potential physiological metrics,
so we can predict irregularity and future
recurrent episodes.

**A comprehensive patent suite**
CHR, technology, and diagnostics

The relationship between psychiatric illness and the circadian pattern of heart rate.
Hans G . Stampfer, Australian and New Zealand Journal of Psychiatry 1998; 32:187-198.

A4

# Clinical Background

| PAST/ PRESENT STUDIES | PARTNERS | ACCURACY | STUDY PURPOSE |
|---|---|---|---|
| **Prospective Clinical Validation Trial**<br>**DX04 DEPRESSION - Prospective Study**<br>May 2018<br>**220 patients** | **8 clinical study partners** | **70% (56-84%)** | Prospective, blinded, case controlled, cross sectional clinical validation study to support the FDA De Novo submission as an aide in the diagnosis of depression in a normal environment |
| **Retrospective Data Analysis**<br>**Retrospective PSG+HRV in sleep lab for DEPRESSION**<br>November 2016<br>**889 patients** | Ottawa University | 86% | Retrospective, un-blinded analysis to identify depressed from non-depressed subjects in a controlled sleep lab environment using PSG + HRV |
| **Proof of Concept**<br>**MACH-3 Depression - Prospective study**<br>August 2017<br>**60 patients** | JOHNS HOPKINS MEDICINE | 82% | Prospective, proof of concept study using HRV to diagnose depression In a primary care setting |
| **MACH-2 DEPRESSION - retrospective study**<br>December 2016<br>**26 patients** | JOHNS HOPKINS MEDICINE | 81% | Retrospective hypothesis study to identify depressed patients |
| **Foundational Learning**<br>**SLEEP STAGING Observational Study using ECG Data**<br>June 2016<br>7,500 subject sleep records | JOHNS HOPKINS MEDICINE | 86-95% | Retrospective data analysis to identify sleep staging using ECG data |

Versus 33-50% – Diagnostic accuracy in the Primary Care Setting[1]
(1) Depression in Primary Care Vol 1: U.S. Department of Health

# Clinical Validation DX04 FDA Study

| | ACCURACY | CONFIDENCE INTERVAL (95%) |
|---|---|---|
| **Medibio DX04** | **70%** | **56-84%** |
| **Physician Inter-Rater Reliability**[1,2] | | **46-64%** |

# Clinical Validation

**CORPORATE HEALTH**

Providing personalised solutions in employee and organizational mental health.

**STRESS**

~64 million lives[1]

**CONSUMER HEALTH**

Empowering consumers to track and manage mental health.

**STRESS**

~266 million lives[2]

**INTEGRATED HEALTH**

Designing clinical decision support systems that enable clinicians to monitor and manage their patient populations.

**DEPRESSION**

~450 million lives[3]

1. Based on employment in USA and Australia
2. Based on adult population in USA and Australia
3. World Health Organization's global population of mental disorders

# Corporate Health App



## ilumen™

An objective digital biometric analysis and mental wellness assessment provided to the employee, paid for by their employer.

- Mental wellness survey and assessment
- Biometric monitoring with history tracking
- Optional telepsych debriefing of results
- Communications toolbox for rollout
- Organisational dashboard analytics
- Recommendations for employer

**THREE-STEP PROCESS**



ASSESS     CONNECT     DISCOVER

1. Based on employment in USA and Australia
2. Based on adult population in USA and Australia
3. Based on people in the world currently suffering from a mental health condition

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**CORPORATE HEALTH**

# Corporate Health App



**REAL-TIME ORGANISATIONAL DASHBOARD**

Organizational Dashboard
Status: **LIVE**
Filtering results by:

GENDER:   MALE   /   FEMALE   /   NON-BINARY

AGE:   18-24   /   25-34   /   35-44   /   45-54   /   55+

- Detailed analytics to Corporate Customers at Organisational level
- De-identified aggregate data to enable informed decision making
- Ability to filter and view demographical subsections (eg. Females, aged 18-35)
- Improve team performance and employee well-being

# Corporate Health App



**ilumen™**
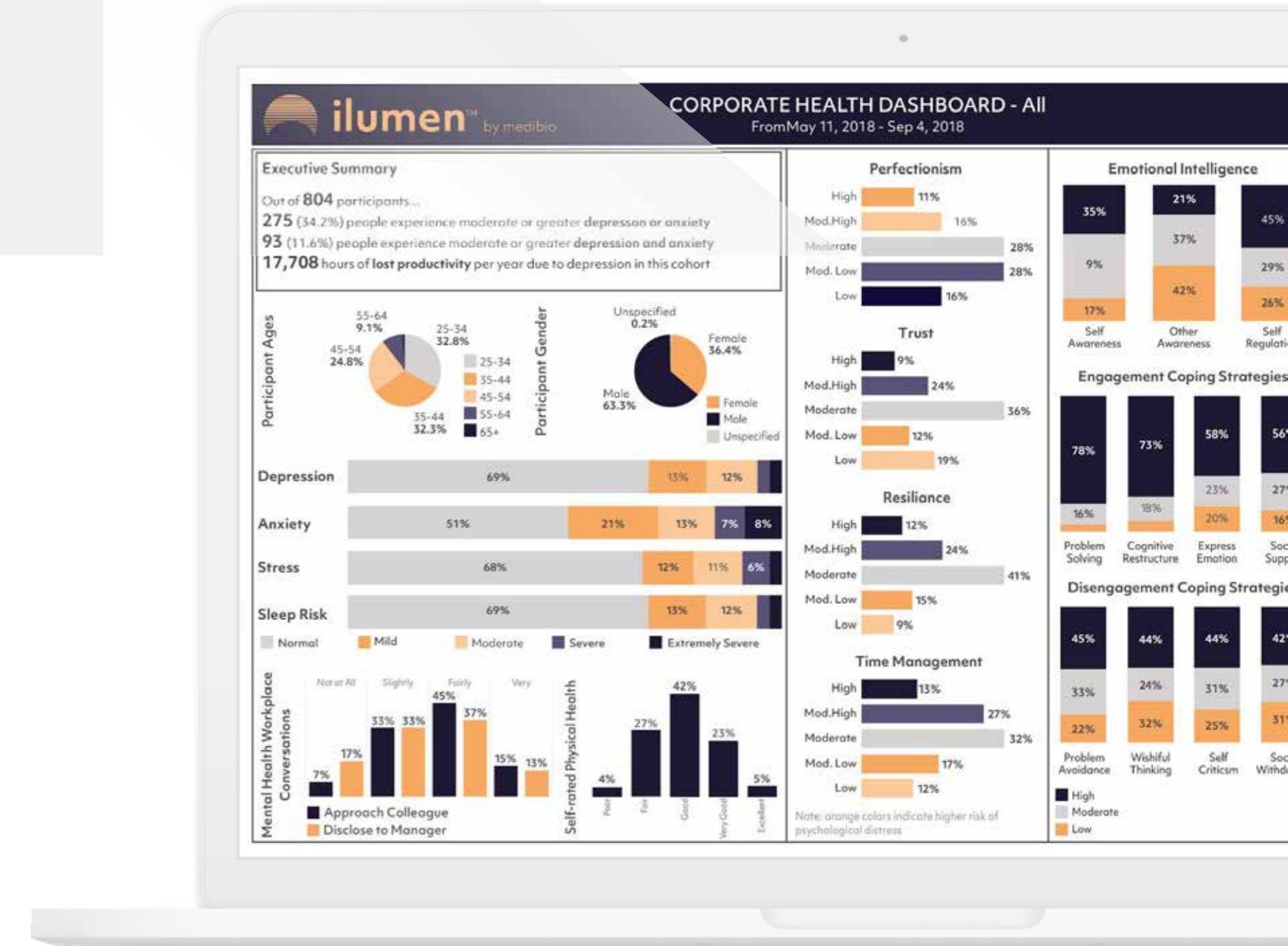
## WHY IT'S NEEDED

In any workforce there are various levels of stress that can affect individual/team mental wellness.

**Employers are**

- Increasing pressure to meet internal/external targets and promoting high performing culture
- Requiring higher levels of mental fitness & time requirements at work and at home
- Expecting frequent travel and project deployment

**...While managing**

- Wide geographical distribution
- Turnover
- Well-being programs that aren't data-driven or specific to your organisation

## HOW IT WORKS
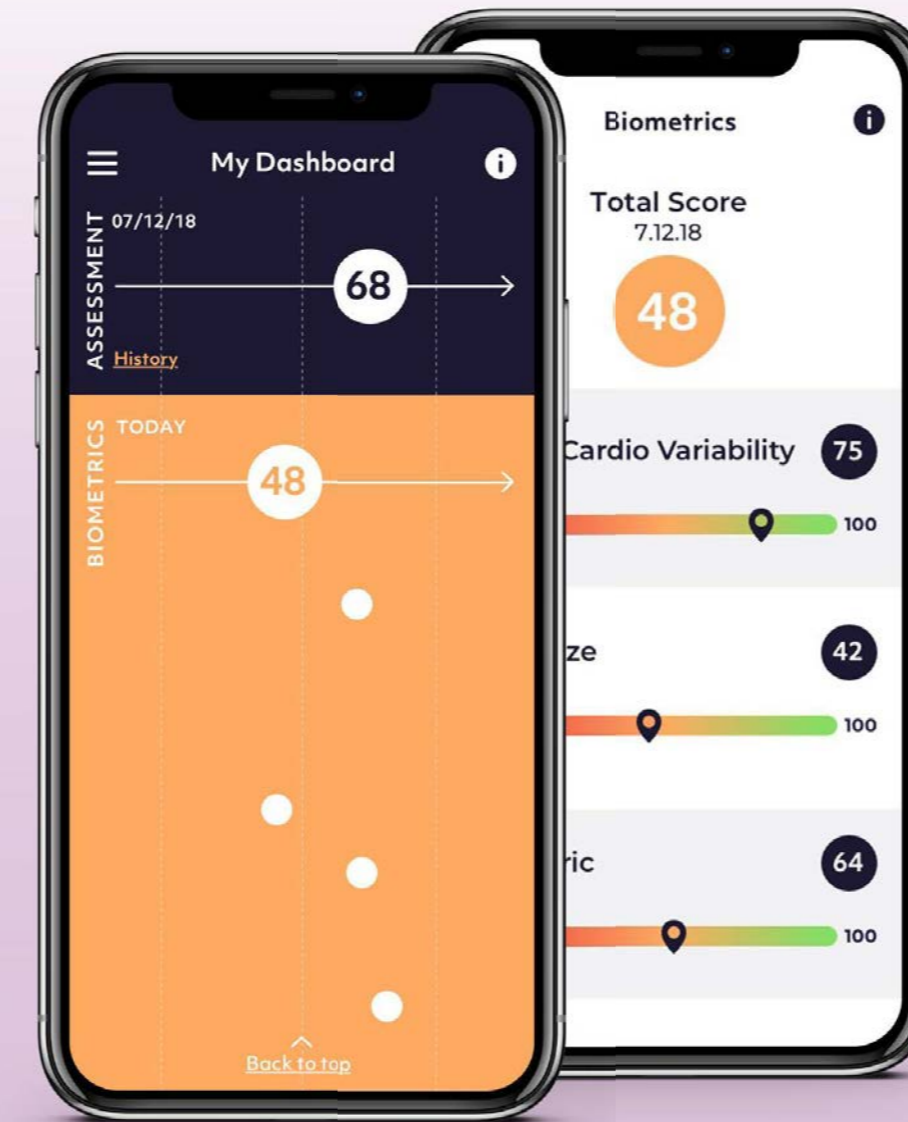
**Employees:**

- Employees track biometrics over time with a wearable device
- Access to mental wellness assessments via mobile or web
- Learn about strategies to better cope with managing life at work, personal development plans, stress, and strain
- Empowered to measure, monitor, and improve wellness

**Organizations:**

- Dynamic understanding - know what your workforce needs AND how to help
- Optimize workforce performance, minimize risk, and offer better care for employees

## WHAT IT DOES

**Employees:**

- Track and monitor wellness
- Improve through tailored resources
- Identify positive influences of personal lifestyle modifications

**Organizations:**

- Access a de-identified dashboard of employee well-being
- Make informed decisions based on workforce data
- Monitor impact of decisions made, programs implemented
- Provide metrics on workforce capability to clients, suppliers, insurers etc.

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**CORPORATE HEALTH**

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**THANK YOU**

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LOOKING AT
MENTAL HEALTH,
**OBJECTIVELY**