



## **Investor Update**

May 27, 2019

LOOKING AT  
MENTAL HEALTH,  
**OBJECTIVELY**

## Forward Looking Statements

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We are a health technology company pioneering the use of objective measures to aid in the early detection and screening of mental health conditions.

## Corporate Structure

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

<b>Market Cap</b>	<b>AU\$2.79M</b>
Share price <i>as of 24 May 2019</i>	AU\$0.011
Shares on Issue	249M
Shares on issue –fully diluted <sup>1</sup>	138M
<b>Cash<sup>1</sup></b>	<b>AU\$2.9M</b>

1. Convertible notes have mandatory conversion June 2020

2. Cash balance as of 31 March 2019

medibio

LOOKING AT  
MENTAL HEALTH,  
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## Re-Startup Strategy

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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™
  - Australia
  - Interest within U.S. growing quickly

## 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



**MELANIE LEYDIN**  
Director & Joint Company Secretary  
B. Bus, CA



**MATHEW WATKINS**  
Joint Company Secretary  
B. Bus, CA

## Executive Team

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



**PEGGY MORGAN**  
Corporate Controller



**ARCHIE DEFILLO**  
Chief Medical Officer

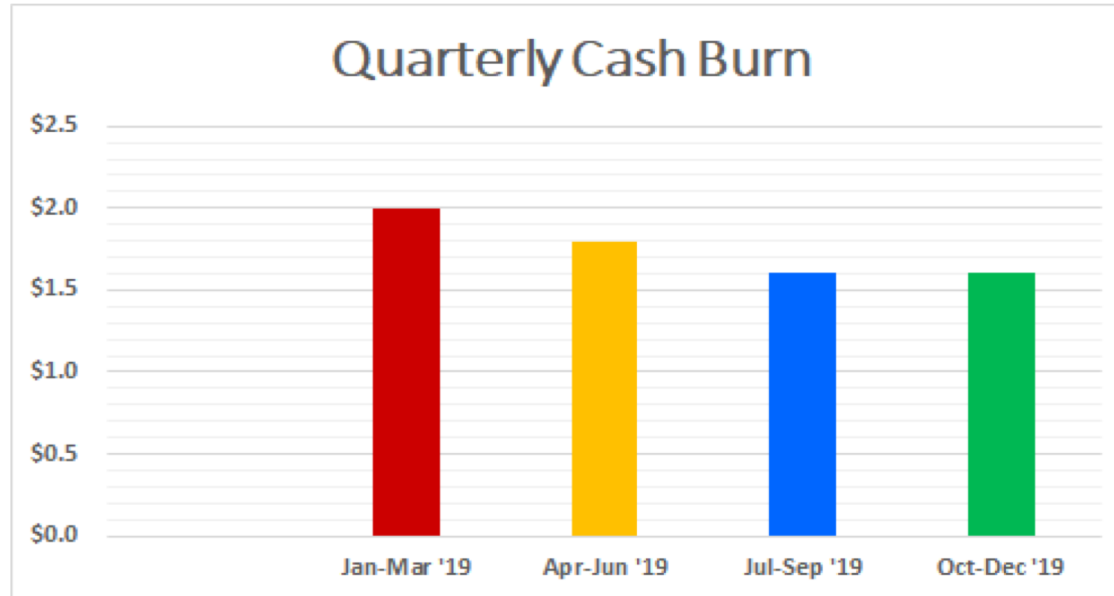


**JENNIFER SOLITARIO**  
Senior Vice President Corporate Health



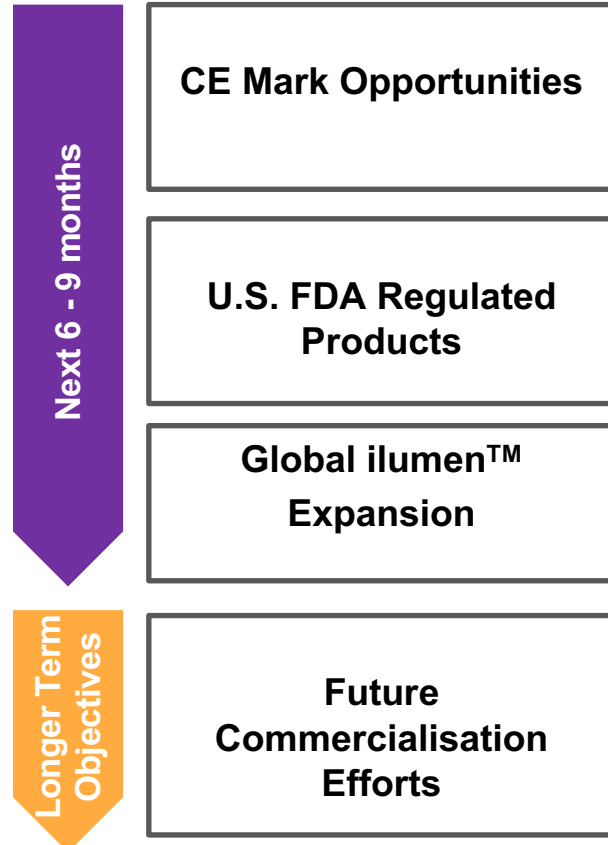
**LINDSEY HAGAN**  
Vice President Strategy & Business  
Development

## Quarterly Cash Burn



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

# Business Objectives – Regulated & Unregulated Product Pipeline



- Leverage recent ISO13485 re-certification with expanded scope
- Finalise 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
- Retained DuVal & Associates as FDA Counsel
- Identified long-term FDA strategy
- Filing new De Novo in late 2019
- Provide an early screening tool for presence of depressive symptoms
  - Use of data from existing clinical workflows (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

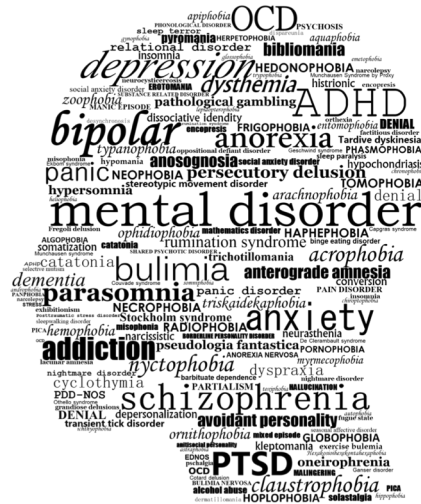
## Product Overview – U.S. Regulated Pathway

### FDA De Novo

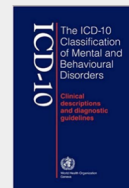
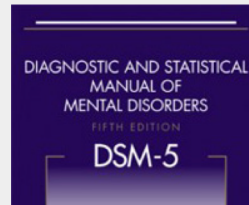


- ▶ De Novo to be filed in late CY2019 with end point anticipated in late CY2020
- ▶ Improve Clinician assessment of patient's mental health
- ▶ Company has begun positive and open dialogue with FDA
- ▶ FDA is helping to guide us through the process and has provided excellent directional feedback about our technology.

# Mental Health Diagnosis



Unlike diabetes or cancer - there is no medical test that can provide a diagnosis of mental illness



Standard of Care for Diagnosis and Treatment

## Mental Health - Diagnosis Delay

“Median delays among cases eventually making contact ranged from 3.0 to 30.0 years for anxiety disorders, from 1.0 to 14.0 years for mood disorders”

*World Health Organization*

Of the population with MDD, only 35 percent are treated within the first year of developing symptoms; for others it can take 4 years or more.

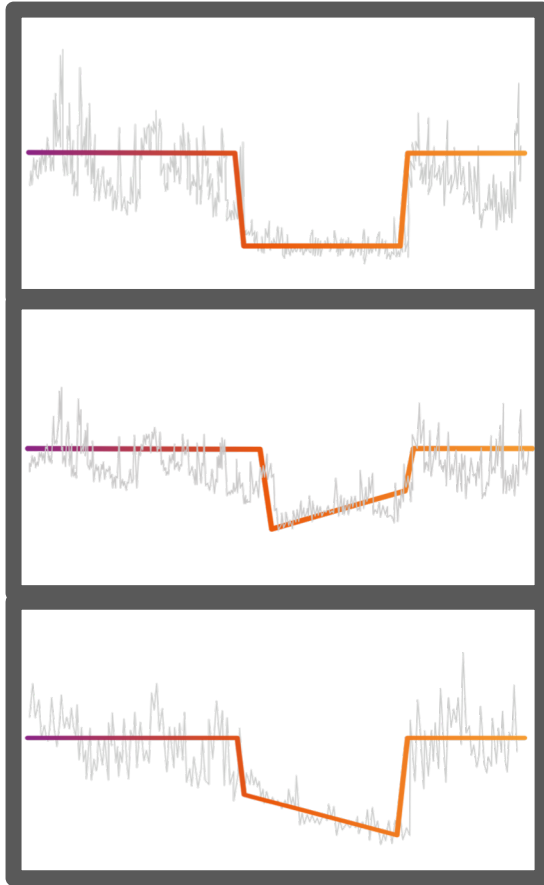
*Mental Health America*

“People with bipolar disorder wait for an average of 13.2 years before they are diagnosed, and often spend years receiving treatment for other conditions”

*Royal College of Physicians*



# Circadian Rhythms and Mental Illness



**Normal**

**Depression**

**Anxiety**

References:

*The Relationship between Psychiatric Illness and the Circadian Pattern of Heart Rate* - Stampfer, H. G. (1998). Australian and New Zealand Journal of Psychiatry.

*Variations in circadian heart rate in psychiatric disorders: theoretical and practical implications* - Stampfer, H. G. (2013). Chronophysiology and Therapy.

**New De Novo submission will have “Depressive Burden” as the indication of use. Depressive Burden is the cumulative load of depressive symptoms upon an individual.**

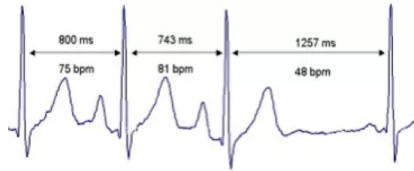
**The Beck Depression Inventory (BDI-II) is a measure of the severity of depression symptoms during a depressive episode. This is a subjective measure of depressive burden.**

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

# The Biometrics – Used by Medibio's Proprietary Algorithms

## Types of Data Collected

### Cardiac



Heart Rate Variability



Circadian

### Brain



Electroencephalogram

### Pulmonary



Respiration

## Sources of Data

### Polysomnography



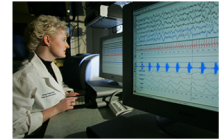
Lab and In-home Studies

### Wearables



## Location

### Laboratory



Sleep Centers

### In-vivo (In Life)



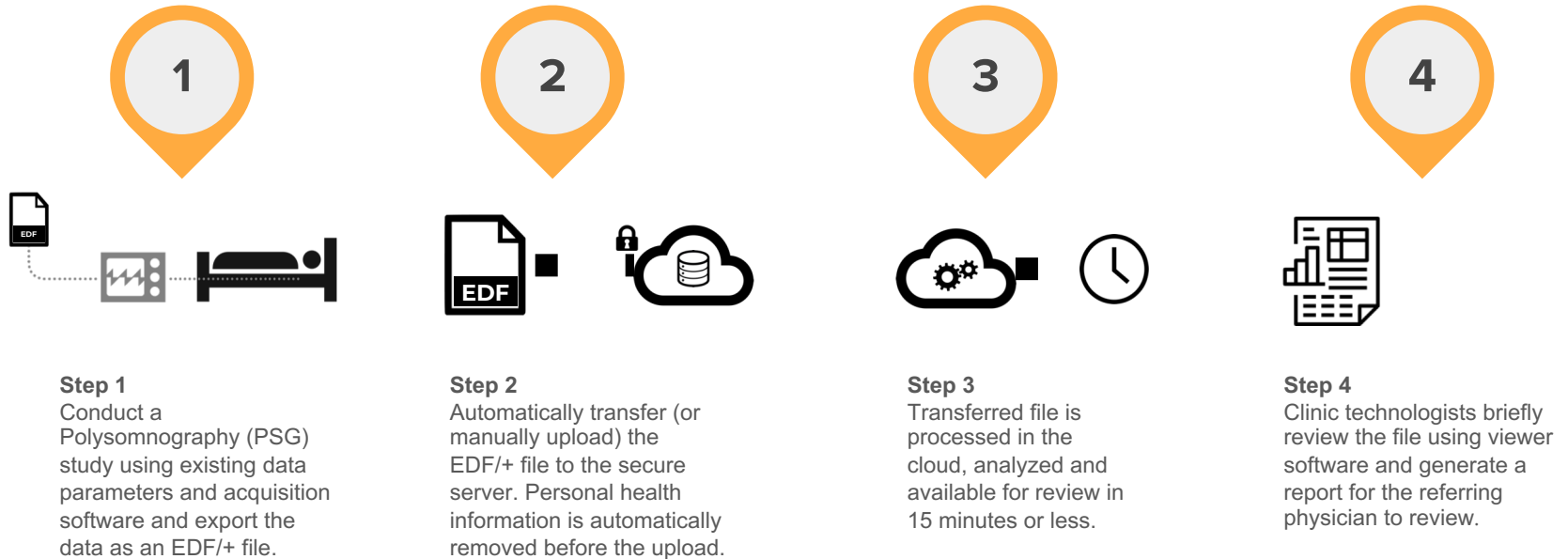
Calm



Sleep


# Product Overview


The Medibio Platform will integrate with existing sleep study systems to analyze multiple channels of physiological data to calculate a mental health risk score. A pipeline of products is planned which will offer additional mental health reporting features to the referring physician.




## U.S. Sleep Studies Market Data

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- 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>

1. <https://www.forbes.com/sites/daviddisalvo/2015/08/06/how-the-sleep-industry-is-making-billions-from-your-lack-of-shuteye/#349d60cf2542>

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

3. <https://www.novasom.com/for-patients/sleep-apnea-related-conditions/depression/>

\* Assumes 80% utilisation

## Potential Commercialisation & Partnership Opportunities

Company	Focus	Organization Revenue	Commercial Potential
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

**PHILIPS**



**natus**



# Product Overview – Corporate Health



ilumen

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

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

## THREE-STEP PROCESS



ASSESS



CONNECT



DISCOVER

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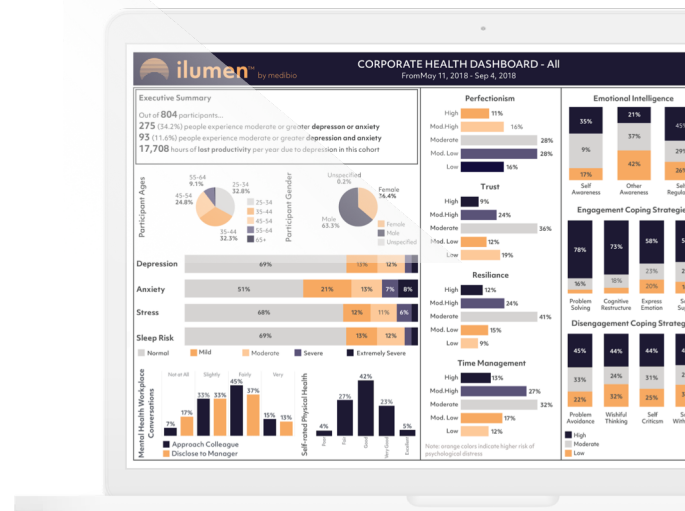


# Product Overview – Corporate Health



## ORGANISATIONAL DASHBOARD

- Detailed analytics to Corporate Customers at Organisational level
- De-identified aggregate data to enable informed decision making
- Improve team performance and employee well-being



# Product Overview – Corporate Health



## WHY IT'S NEEDED

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

### 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

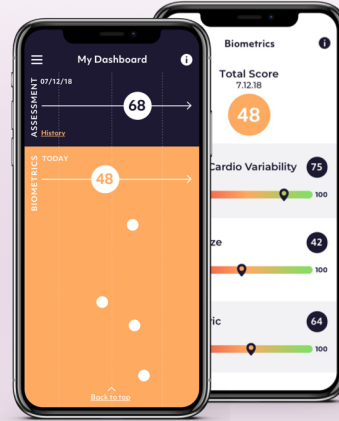
## HOW IT WORKS

### Employees:

- Employees track biometrics over time with a wearable device
- Access to mental wellness assessments via mobile or web
- Empowered to measure, monitor, and improve well-being

### Organisations:

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



## WHAT IT DOES

### Employees:

- Track and monitor well-being
- Improve through access to resources
- Identify positive influences of personal lifestyle modifications

### Organisations:

- Access a de-identified dashboard of employee well-being
- Make informed decisions based on workforce data
- Monitor impact of decisions made, programs implemented

# Product Overview – Corporate Health Commercial Opportunities



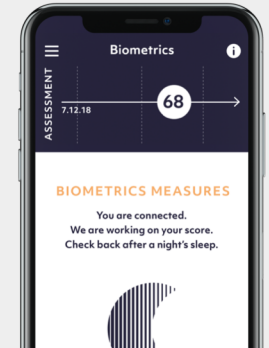
## Global

### ilumen™ in Corporate Health Market



- ▶ App based system provides feedback to individual
  - De-identified aggregate feedback to Corporate partner
- ▶ Pilot programs marketed to large corporations with goal for annual license agreements.
  - One pilot completed with high participation
  - Proposal to engage for new 1-year program
  - Per employee license fee pricing structure moving forward
  - In discussion with large multinational company – 600,000+ employees

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



# Product Overview – Corporate Health – Commercial Opportunities

## Global Enquiries

### Corporations

- Well-being programs

### Pharma Companies

- Partnership/Development opportunities

### Sports/Athletics

- Partnership/Development opportunities

## Commercial Potential

### Corporations

- Per employee license fees

### Pharma Companies

- Fee for specific development
- License fees for platform

### Sports /Athletics

- Fee for specific development
- License fees for platform

## THREE-STEP PROCESS



ASSESS



CONNECT



DISCOVER

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# Milestones



## **CY 2019 Q3**

- New ilumen™ programs in AUS
- Potential 1-year program for ilumen™
- New CE Mark
- New Clinical Partnership with world renowned university sleep research center
- Published research and white papers

## **CY 2019 Q4**

- New De Novo submission filed with FDA
- Potential first sports client for ilumen™
- Published research and white papers

## **CY 2020 Q1**

- Potential first U.S. ilumen™ client
- Published research and white papers

## **CY 2020 Q3**

- FDA De Novo Clearance
- Published research and white papers



**THANK YOU**

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**[medibio.com.au](https://medibio.com.au)**

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