PITT STREET RESEARCH

Medibio Ltd

Share Price: A$0.01

Unique proposition for mental health diagnostics

Medibio Ltd (ASX: MEB) is a mental health technology company that analyses heart rate and heart rate variability patterns during sleep to diagnose mental illness. Based on about 20 years of scientific research, Medibio has developed novel, data-driven and scalable solutions to objectively screen for mental health disorders.

Current standard of care lacks objectivity

Depression is a large market globally, with c350 million people of all ages suffering from depression. The major drawback with the current standard of care is due to their lack of objective measurement, which may often lead to sub-optimal diagnosis and treatment of depression, the outcome of which could see depression to recur and result in a life-threatening disorder.

2021 is a transformational year for Medibio

Medibio is exploring ways to develop and commercialise its two regulated products, namely MEB-001 and MEBsleep. On MEB-001, the company is undertaking clinical trials to validate it as a depressive burden platform. We expect MEB-001 to be the game changer for the company due to its potential to revolutionise the way we research, diagnose and treat depression. On MEBsleep, Medibio is ready to commercialise this sleeping staging algorithm in the sleep research market, which could see early revenues to become visible in H2 2021.

Medibio is also working hard to drive commercialisation of its non-regulated products namely, ilumen and Consumer App. We are encouraged by the company landing its first revenue generating contract with a Compass Group subsidiary company based in the UK for use of its ilumen product. We see this initial deal representing traction from the Compass Global Agreement and paving the path for many more future orders from Compass Group companies across the world.

Additionally, Medibio is also working towards the commercial launch of its Consumer App, which will be a unique stress app with both biometric and psychometric assessments of the user's stress. The company expects to launch this product in the US in H2 2021, which should see initial revenues to flow through.

Valuation range of A$0.05 – 0.08 per share

We value MEB at A$0.05 per share base case and at A$0.08 per share bull case using a DCF methodology. Key risks we see include: (1) delays in receiving regulatory approvals for MEB-001; (2) lower adoption rate of MEBsleep and MEB-001; and (3) loss of momentum in corporate investments for mental health due to economic slowdown.

ASX: MEB

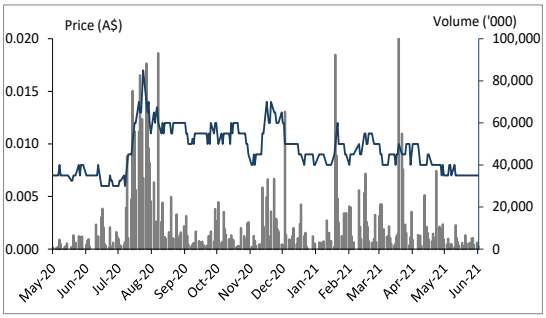
Sector: Health Care Equipment & Services

3 June 2021

Market Cap. (A$ m)	12.6
# shares outstanding (m)	1,795.1
# shares fully diluted (m)	2,944.3
Market Cap Ful. Dil. (A$ m)	20.6
Free Float	80.3%
52-week high/low (A$)	0.017 / 0.005
Avg. 12M daily volume ('1000)	11,995.7
Website	www.medibio.com.au

Source: Company, Pitt Street Research

Share price (A$) and avg. daily volume (k, r.h.s.)



Source: Refinitiv Eikon, Pitt Street Research

Valuation metrics	
DCF fair valuation range (A$)	0.05 – 0.08
WACC	14.4%
Assumed terminal growth rate	2.0%

Source: Pitt Street Research

Analyst: Stuart Roberts, Cheng Ge

Tel: +61 (0)447 247 909

stuart.roberts@pittstreetresearch.com

cheng.ge@pittstreetresearch.com

Disclosure: Pitt Street Research & its directors own shares in Medibio Ltd.

Table of Contents

Introducing Medibio, ASX: MEB	**3**
Ten reasons to look at Medibio	**5**
Description of the technology	**6**
Regulated business	**8**
MEBsleep – the software that uses sleep staging algorithms	***8***
MEB-001 – the depressive burden platform	***9***
Unregulated business	**10**
ilumen – the fast-growing corporate health solution	***10***
Poised to foray into consumer mass market	***13***
Built on a robust clinical foundation	**14**
Proof of concept	***14***
Significant validation of technology	***15***
Commercialisation plans on fast track	**15**
CE Mark approval granted, US FDA approval underway	***15***
Gaining traction in the unregulated market	***16***
Mental health concerns are gaining importance worldwide	**17**
Valuation	**21**
Solid leadership team	**23**
Appendix I – Major shareholders	**25**
Appendix II – Capital structure	**25**
Appendix III – IP position	**25**
Appendix IV – Papers relevant to Medibio	**27**
Appendix V – Companies comparable to Medibio	**30**
Appendix VI – Analyst Qualifications	**31**
General advice warning, Disclaimer & Disclosures	**33**

Introducing Medibio, ASX: MEB

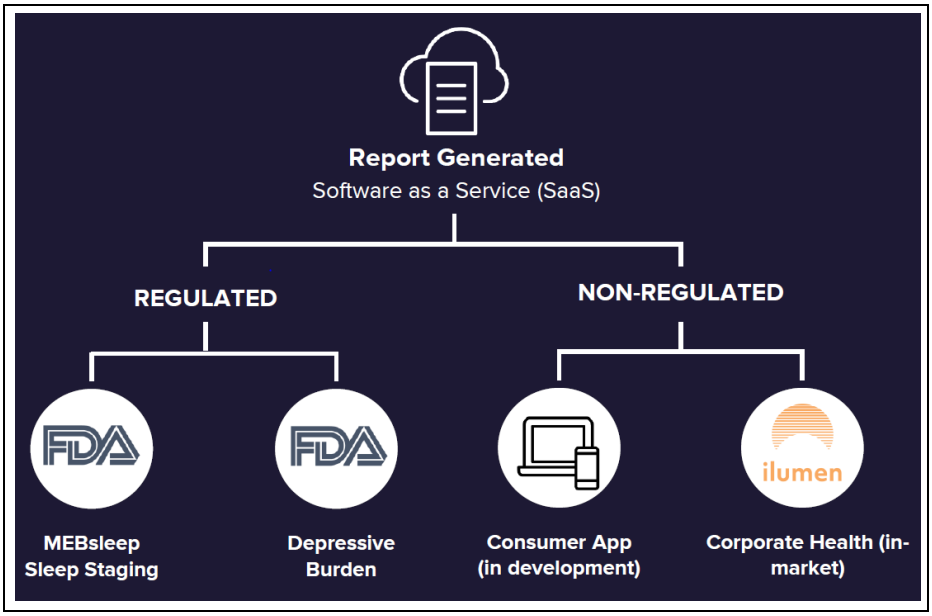
Medibio is a Melbourne and Minneapolis-based healthcare technology company. It operates through two business units – regulated and non-regulated (Figure 1). Through the regulated business unit, Medibio targets the healthcare provider market through its sleep staging software – MEBsleep. The company has received CE Mark approval and is currently working with the US FDA to re-submit its 510(k) application, for this solution.

Medibio provides solutions for early screening of mental health conditions through physiological measures such as heart rate

The company is also developing a depressive burden platform – MEB-001 – which will combine the MEBsleep algorithms with overnight heart rate and heart rate variability algorithms to support depressive burden analysis. Medibio received Institutional Review Board approval in October 2019 to conduct the Sleep Analysis of Depressive Burden (SADB) study and is currently conducting trials in sleep clinics in North America.

Under the non-regulated business unit, Medibio provides its solution, ilumen, to businesses for the early screening and management of their employees' mental well-being. It is also developing a mobile app for the consumer segment, which will help assess stress levels of users through biometric information (such as heart rate, sleep and activity levels to map a person's behaviour) obtained from wearable devices. Medibio expects to have a working prototype of this app by early in 2021, with commercial launch slated for H2 2021.

Figure 1: Medibio's business model



Source: Company

Physiological markers can help identify mental illness

Mental disorders such as high anxiety and depression can impact several systems in our body. Thus, biomarkers indicating abnormal behaviour of the biological systems can help detect certain mental disorders. Behavioral Researchers have linked these disorders to several indicators, including an individual's genetics, physical differences in the brain and even imbalances in gut bacteria. Medibio believes that it has identified observable nocturnal patterns. Heart rate and heart rate variability patterns that suggest mental illness are most obvious during sleep and Medibio analyses these patterns for early detection of mental illnesses.

Mental well-being is increasingly receiving its due importance

Mental wellness has a significant economic impact

- Mental health is gradually receiving more attention and importance from individuals and corporations. The World Health Organization (WHO) believes that mental health is one of the leading causes of disability worldwide. Mental disorders do not just have a health impact but a significant economic impact too. The WHO estimates that anxiety and depression cost the global economy ~US$1tn in lost productivity. It also holds that every US$1 invested in the treatment of common mental disorders can provide up to US$4 in improved health and productivity. It is thus in the best interests of organisations and governments to tackle mental health issues proactively.

Corporates have become more conscious of mental health issues, particularly post COVID-19

- In May 2019, the WHO recognised burnout for the first time as an occupational phenomenon caused by chronic workplace stress. The agency had previously defined burnout as a "state of vital exhaustion," but this is the first time that burnout is being directly linked in WHO's classification of diseases as a work hazard. Consequently, corporations are now beginning to acknowledge the rising concerns around mental well-being of their employees and the benefits of early screening of such disorders. It is also being observed that firms that proactively deal with sensitive movements and issues such as Black Lives Matter, Me Too and mental health end up benefitting from a stronger brand identity among their external stakeholders, including customers.
- The COVID-19 Pandemic has caused significant changes in our personal and professional lifestyles. Across the world, people are living under heightened uncertainty and insecurity caused due to both health and economic issues. With countries restricting the movement of their citizens, individuals are spending more time indoors. The new reality of work from home and virtual classrooms has not only led to physical distancing but also resulted in social isolation. These circumstances have made the general public more susceptible to distress and anxiety. Due to these reasons Medibio is witnessing growing demand for its mental well-being solution, ilumen, which focusses on corporate employees.

Ten reasons to look at Medibio

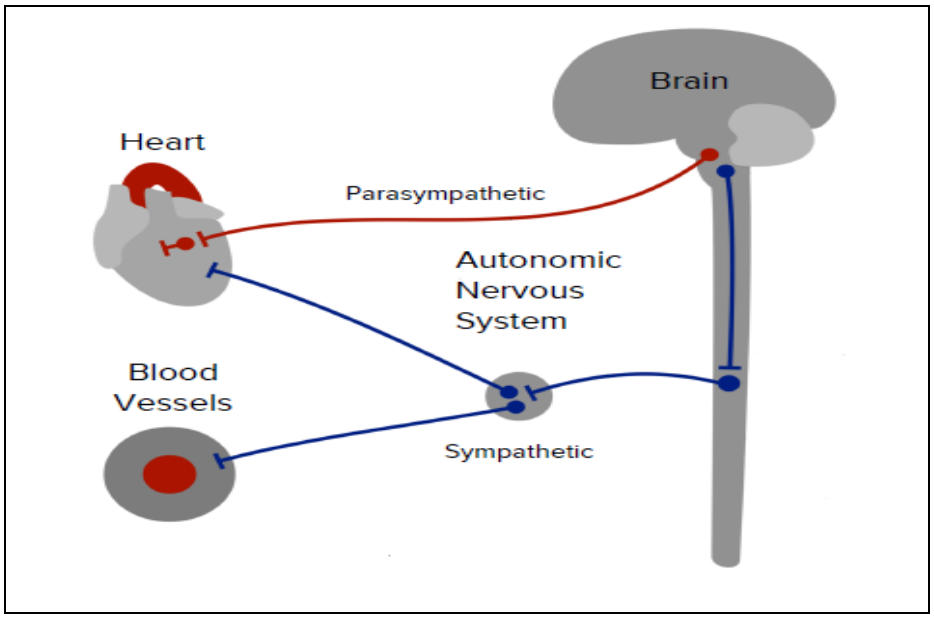
1) **Medibio has developed a novel, data-driven solution to objectively screen for mental health disorders**. Besides being a non-intrusive technology, Medibio's solution is highly reliable and cost-effective, and can be easily administered to patients by primary care personnel.
2) **Medibio's unique sleep-based heart rate technology is patent-protected** and based on over 20 years of research on the correlation between mental health and the patients' heart rate.
3) **Medibio has research partnerships with renowned global universities,** including Johns Hopkins University and the University of Ottawa, which have, through several pilots and clinical studies, aided in the corroboration of its technology.
4) **Barriers to entry**. Besides patent protection, Medibio's vast database of electrocardiogram data, along with corresponding clinical psychiatric diagnoses that has over many years contributed to its intellectual knowhow, poses a significant entry barrier for new entrants.
5) **The company has developed multiple offerings with different target markets and commercialisation routes in mind.** Medibio plans to offer four distinct solutions across its regulated and unregulated business units, and this will potentially allow the company to benefit from diversified revenue streams.
6) **Mental health issues are on the rise, with huge costs to the global economy to the tune of US$1tn annually.** Over 350 million people suffer from depression in the US and Europe alone and this excludes people suffering from high anxiety levels. The key challenge with current diagnostic systems is that they lack objective measurement and are time-consuming. This is where Medibio's solutions can help by providing early and clear screening, which can lead to effective treatment and lower costs to the economy and society.
7) **The company has received CE Mark approval for its solutions in the regulated business segment.** The CE Mark approval has significant revenue implications for the company as it allows Medibio to commercialise MEBsleep across the European Economic Community. Additionally, Medibio is also currently exploring opportunities to sell MEBsleep into the large US sleep research market.
8) **Medibio's corporate mental well-being app, ilumen, continues to gain strong traction among employers,** which augurs well for the company in its early-revenue-generation stage. This target market is being buoyed by structural tailwinds, including the growing acceptance of mental health issues by employers and the emphasis by governments to create mentally healthy workplaces. Further, COVID-19 has played a significant role in making the mental well-being of employees one of the top priorities of corporates. We believe that with the recent blockbuster Compass Group deal for ilumen, Medibio will continue to focus on global organisations and leverage the structural tailwinds.
9) **The current leadership team** of Medibio, including the Managing Director (Claude Solitario) and Chief Medical Officer (Dr. Archie Defillo), possesses significant experience in the fields of healthcare technology and mental wellness, which is a big positive for the company in its commercialisation journey across various solutions. Senior Vice President, Jennifer Solitario, is critical in driving the global commercial success of ilumen and very well-qualified to be leading the charge.

10) **We believe Medibio should be valued higher than its current market value**. Our intrinsic value for Medibio comes out to be A$0.05 per share in the base case and A$0.08 per share in the bull case. We believe re-rating will be driven by three key catalysts: 1) further traction and revenue generation for ilumen, 2) regulatory approvals for MEBsleep and MEB-001 solutions in its regulatory business unit and 3) initial revenues from Consumer App.

Description of the technology

Medibio's technology is based on the premise that the mental health conditions of an individual are strongly linked to the autonomic nervous system (ANS), circadian heart rate, heart rate variability and sleep disturbance (Figure 2). Mental illnesses are associated with some degree of ANS and circadian dysregulation, demonstrated by changes in heart rate and heart rate variability.

Figure 2: Brain and heart health are intimately connected



Source: Company

The ANS comprises a sympathetic and parasympathetic nervous system to regulate the body's unconscious actions:

- **The sympathetic nervous system** stimulates the body's fight-or-flight response to dangerous/stressful situations. The response – also called sympatho-adrenal response – acts primarily on the cardiovascular system and accelerates one's heart rate.
- **The parasympathetic nervous system** is responsible for the stimulation of activities occurring when the body is at rest – 'rest and digest' and 'feed and breed' activities.

Medibio's platform correlates heart rate variations with mental state using advanced algorithms

On witnessing adverse mental conditions – such as depression – the body's parasympathetic activity is diminished, whereas its sympathetic nervous system is hyper activated, thus increasing one's heart rate. In subjects suffering from depression and anxiety, the heart rate normally runs higher than that of normal individuals. The difference in heart rate variations can

thus be leveraged as a psychophysiological marker to distinguish between different mood disorder phenotypes, i.e., anxiety and depression.

The mental health assessment solution developed by Medibio leverages machine learning (ML) and deep learning tools to assess the mental state of a subject based on his/her EEG and ECG data obtained during polysomnography (sleep study). This information is processed and accessed conveniently using a standalone software device or a cloud-based interface. The corporate and consumer apps also provide directions for the usage of a wearable heart monitor (e.g., Garmin and Apple devices) and transfers the monitored data for assessment.

Medibio's platform leverages EEG and ECG data recorded over an entire night to indicate the intensity of a subject's depressive burden. Medibio's technology correlates electroencephalographic and heart rate data with an individual's depressive burden status by using AI algorithms modelled based on historical data stored in a cloud database, which is derived from reference subjects – including subjects with a healthy mental state and those with mental conditions.

Heart rate patterns that can help diagnose mental illness are most evident during sleep

Key benefits of the technology

Medibio's technology offers a multitude of benefits compared with the traditional approach of clinical interviews with patients:

- **Objectivity.** The company's solution provides quantitative and objective screening results for mental disorders based on biomarkers. There is no subjective analysis and interpretation involved in the process.
- **Scalability.** Medibio's technology can be easily administered to patients by primary care personnel and does not necessarily require specialists. The tests on Medibio's system can also be repeated at high frequency. These aspects make the solution highly scalable and cost-effective.
- **Reliability.** Previous early-stage clinical studies demonstrated encouraging results in screening for depressive burden.
- **Treatment efficacy.** Medibio's platform, which is driven by objective data and algorithms, can provide a tailored-management of patients which could improve treatment efficacy, potentially reducing elevated risk for depression episode recurrence and chronicity.
- **Integration with wearable devices.** This technology is easy to use as well as integrate with certain wearable devices for monitoring heart rate in the non-clinical and home environment, making it possible for it to be leveraged by general consumers as per their convenience.

Regulated business

This business currently comprises Medibio's MEBsleep and Depressive Burden platforms.

MEBsleep – the software that uses sleep staging algorithms

MEBsleep's unique features are its speed and accuracy, as it identifies sleep stages in just two minutes vs. 1–2 hours taken by a clinician

The prerequisite for the development of a depressive burden algorithm is the identification of the five key sleep stages of an individual. Medibio has developed the MEBsleep solution (previously known as STAGER - Sleep Staging and Heart Rate Variability Algorithms), which deploys artificial intelligence, machine learning and deep learning algorithms to identify the five important sleep stages of a patient, which eventually aids in the determination of sleep architecture features.

Currently, the identification of sleep stages is performed manually by certified sleep technicians, which is a time-consuming process, is costly and requires years of experience. MEBsleep provides a solution for sleep technicians and doctors to improve patient care and serve larger patient populations without adding to their workload. This sleep staging algorithm potentially opens an opportunity in the area of home sleep testing and monitoring.

While MEBsleep's unique features are its speed and accuracy, it also scores over other sleep diagnostic systems in the following ways:

- Utilises electroencephalogram (EEG)[1] and electrocardiogram (ECG)[2] to automatically score sleep study results, including sleep staging and heart rate variability.
- Saves time w.r.t. scoring and analysis, as up to 100 files can be analysed simultaneously.
- Has similar accuracy than human raters, considered the gold standard.
- May lead to increase in sleep centre volume and decreased backlog for studies that need to be scored by human raters.

In order to optimise the STAGER algorithms, a two-stage 'evaluation' process was designed by the company. While 'Evaluation Stage 1' tested STAGER against three human raters, 'Evaluation Stage 2' tested positive and negative percent agreement between STAGER and three expert human raters. Beside this, Medibio tested the consistency of the algorithm's performance by processing signals from different sleep centres. 'Evaluation Stages 1 and 2' were performed using two sets of separate and distinct 40,000 sleep epochs[3].

STAGER has been developed and tested using more than 1 million epochs in over 1,000 individuals. It has shown an overall accuracy of 80% (Figure 3), which exceeds the accuracy of the chosen predicate device and is comparable to the accuracy of human raters.

[1] An electroencephalogram — abbreviated as EEG — is a test that detects abnormalities in brain waves, or in the electrical activity of the brain.
[2] An electrocardiogram — abbreviated as ECG — is a test that measures the heart's electrical activity.
[3] An epoch is a 30-second sleep interval.

Figure 3: Results of 'Evaluation Stages 1 and 2'

	STAGER Average Agreement with the 3 Human Raters	Average Agreement among the 3 Human Raters
Wake	86%	88%
N1	36%	49%
N2	79%	80%
N3	92%	82%
REM	89%	82%
Overall	80%	79%

Source: Company

Notably, MEBsleep is able to identify sleep stages in minutes compared with 1–2 hours taken by a sleep technician (considered the gold standard), Based on this outstanding characteristic, the company submitted the technical file for MEBsleep for European CE Mark approval in August 2020 and has subsequently been granted CE Mark approval in January 2021.

The successful grant of the CE Mark approval will now allow Medibio to start commercialising its MEBsleep device across the European Economic Community. Given Medibio is able to secure a commercialisation partner, it should see itself generating a new revenue stream additional to its current ilumen revenue.

Additionally, Medibio is also presently exploring opportunities to sell MEBsleep into the US sleep research market. The revenue model will be based on a master license for one user with the option of additional users, followed by a price per file analysed.

In March 2021, Medibio reported that two scientific abstracts describing MEBsleep have been accepted to present at SLEEP 2021[4]. Sleep 2021 is the premier world forum for the presentation and discussion of the latest developments in clinical sleep medicine and attended by worldwide expert sleep professionals. We believe this acceptance will strongly enhance MEBsleep's visibility in the sleep research market worldwide.

MEB-001 – the depressive burden platform

MEB-001 provides an objective measure of depressive burden

Medibio is developing algorithms and a related software platform, collectively called MEB-001, which aims to provide clinicians with an objective and data-driven approach to support the diagnosis of depression, based on patients' own biological data.

The depressive burden (mental health) platform consists of three main components:

- MEBsleep, the sleep staging algorithm, overlaid by;
- Resting heart rate and heart rate variability algorithms, leading to;
- Depressive burden analysis and probabilistic determination.

The prime objective of MEBsleep is the identification of sleep stages, which is a crucial part of this platform. MEB-001 analyses physiological signals,

[4] Sleep 2021 will be the 35th annual meeting of the U.S. Associated Professional Sleep Societies and the American Academy of Sleep Medicine, to be held virtually on June 10-13, 2021.

particularly EEG and ECG, obtained from polysomnography (PSG)[5]. This medically-graded software library automatically scores sleep-study results and autonomic modulation throughout sleep stages to distinguish the presence of depressive burden, which typically refers to the amount of depressive symptoms.

In October 2019, SADB was approved by the Institutional Review Board (IRB). Post the approval, Medibio initiated the SADB trial in December 2019, with the objective to identify clinical depressive burden in patients with sleep disturbance who participate in a study in a sleep clinic. The goal of the SADB trial is to clinically validate MEB-001 as a medically graded software library.

The goal of the SADB trial is to clinically validate MEB-001 as a medical device

During the SADB trial, data analysis is being conducted for every 50 patients enrolled and compared to clinical questionnaires such as BDI-II (Becks Depression Inventory) and PHQ-9 (Patient Health Questionnaire 9). The outcome of this analysis will be utilised for a pre-submission meeting with the FDA. The purpose of the meeting is to agree on the goals and endpoints before initiating the final larger validation (pivotal) trial, which will then form the basis of the De Novo submission. This 'Pivotal Study' is expected to require about 300-400 patients.

In order to expedite SADB trial, in October 2020, Medibio inked a clinical trial agreement with MedBridge Healthcare LLC, a leading provider of sleep laboratory management services in the US. This agreement is an attempt to make up for lost time due to COVID-19-induced lockdowns when sleep clinics were closed for about three months and SADB trial came to a halt. On the commercial front, Medibio is aiming to attach a depressive burden report with current sleep report. Medibio's report will permit physicians to better direct treatment paths for patients screening positive for depressive burden. It is estimated that there are ~3.5 million OSA tests conducted each year in the US, which augurs well for Medibio.

Unregulated business

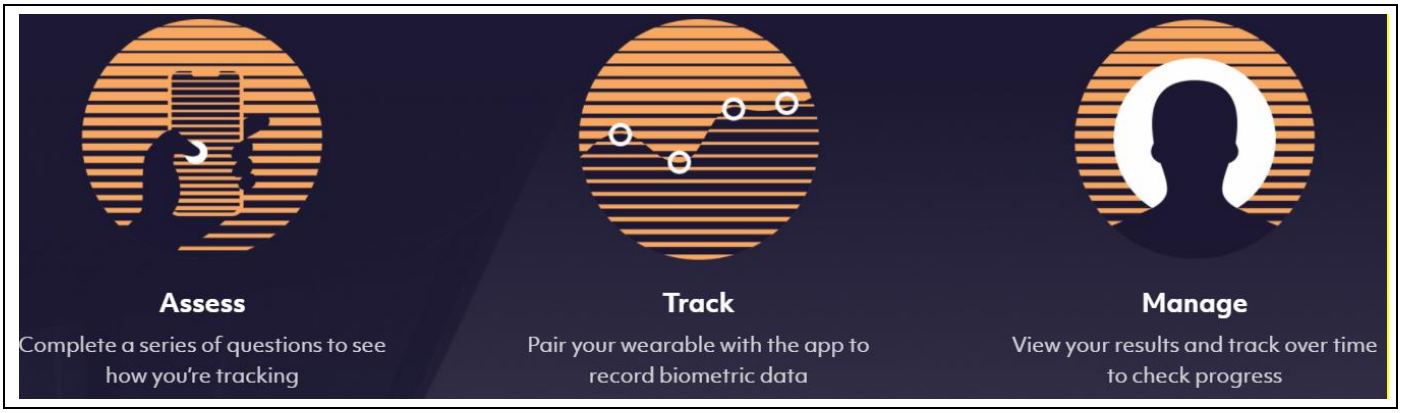
This business comprises Medibio's ilumen and consumer app platforms.

ilumen – the fast-growing corporate health solution

In October 2018, Medibio launched ilumen, the second generation of its corporate product targeting mental wellbeing. ilumen is a unique data-driven mental well-being programme designed to help evaluate and monitor the mental wellbeing of employees. It provides employers with real-time aggregated dashboards of their workforce's results to better manage (Figure 4) the mental well-being of their employees and measure the impact of their mental health initiatives. The interface can be monitored through an app/website with biometrics being tracked through wearable technology. ilumen provides objective feedback to help employees take an active role in managing their mental wellness. It combines psychometric evaluations with the ability to track biometrics using Garmin and Fitbit wearable devices. ilumen also offers access to personalised resources to employees for educational purposes.

[5] Polysomnography is a sleep study designed for obstructive sleep apnea diagnosis, and similar sleep disorders. The test records parameters such as brain waves, heart rate, breathing, eye and leg movements, during sleep.

Figure 4: Three-step process to manage mental wellness of employees



Source: Company

In its first corporate engagement after launch, the ilumen platform was offered to 8,000 employees of a large firm in Australia for a six-week period, for a contract value of A$30,000. Out of the 1,675 registered participants, 26% were identified by the platform as presenting symptoms of depression or anxiety in moderate to severe ranges. After successfully demonstrating the stability of its ilumen platform through its pilot programmes, Medibio is now offering this solution on an annual subscription basis.

Key client wins validate the usefulness of ilumen

ilumen's appeal in its target market is on the rise, as evidenced by its contract wins in the past two years. We think that this solution will provide significant revenue opportunities to Medibio in the near term, and this will go a long way in supporting its other programmes and growth plans.

Medibio has signed key deals with PwC Australia, Stantec Australia and Compass Group for its ilumen offering

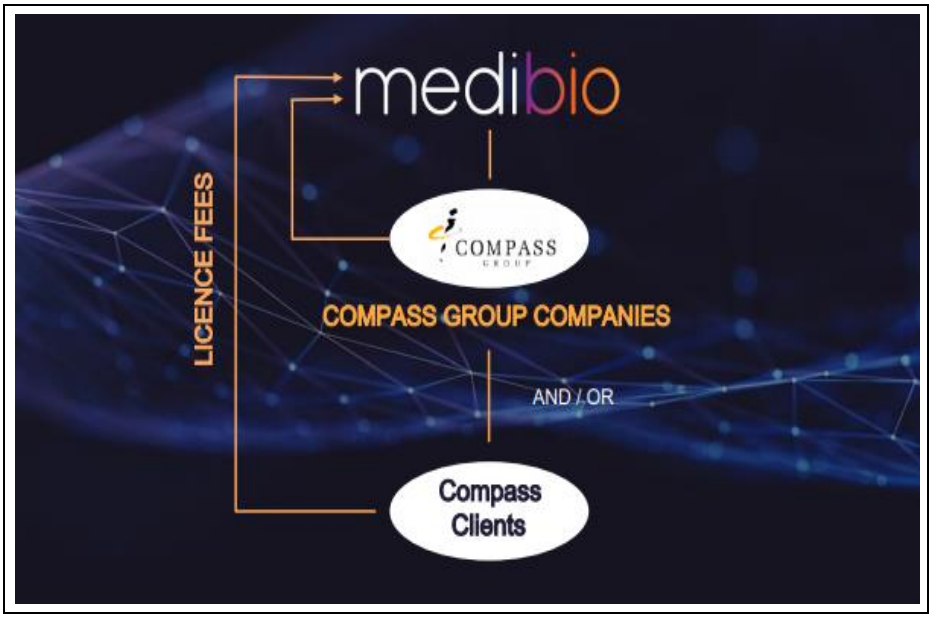
In October 2019, Medibio inked its first annual licence agreement with PwC Australia to provide access to ilumen. About 9,000 employees of PwC Australia had access to ilumen for 12 months. Due to the positive experience with ilumen, PwC has recently extended its licence for another 12 months.

In February 2020, Medibio signed a commercial agreement with Stantec Australia, a global engineering firm, to provide ilumen to 1,500 personnel in Australia, New Zealand and India for 12 months.

Signed a critical three-year licence and services agreement with Compass Group

In November 2020, the company has signed a landmark three-year licence and services agreement with Compass Group for ilumen. Compass Group is the largest food service organisation in the world, with 600,000 employees globally (pre-COVID). The agreement licenses the use of ilumen to Compass Group firms, as well as their end clients. Key clients of Compass Group include Google, Coca Cola, Chevron, Shell, American Express, HSBC, Bank of America and Nike. In return, Medibio will receive an annual licence fee (Figure 5) from each Compass/client firm that implements the ilumen product. This deal is expected to have significant revenue implications considering the sheer number and size of the companies being serviced by ilumen. The license fee will be derived depending on the number of employees and charged annually based on the workforce of each enrolled company, irrespective of the employee participation rate. The agreement also entails a 'sliding scale fee' structured to encourage high usage and maximise participation. This deal is a result of the four pilot programmes that Medibio ran with Compass Group in the past two years. Medibio had registered healthy participation rates across the four pilot studies, with 60–71% of the target workforce volunteering for the studies.

Figure 5: Compass Group reseller agreement



Source: Company

The latest Compass Group deal is in sync with Medibio's commercial roll-out plans for ilumen, wherein it will focus on global organisations that will act as resellers on a revenue-sharing basis. Medibio is in discussions with a number of corporations, and health and wellness providers post the successful completion of paid pilot programmes.

ilumen to enter the UK market

Ilumen can be used to complement a company's existing mental health programme

In March 2021, Medibio received a purchase order from Compass Group to commence the rollout of ilumen to the Compass UK workforce that involves ~1,000 employees, effectively marking the first revenue generating Compass contract. Although this deal will see ilumen to be deployed in only a portion of the UK workforce, we believe it paves the path for Medibio to receive many more purchase orders from Compass companies across the world.

One of the key benefits of ilumen is that it can be used to complement a company's existing mental health programme. As per the Australian Federal Government's Productivity Commission Report into Mental Health, released in November 2020, though most companies provide Employee Assistance Programmes (EPAs), it is difficult to measure their efficiency. In our view, this is where ilumen can play a vital role. For instance, Stantec use the application as part of their overall mental health programme, whereby ilumen provides Stantec's management with de-identified data points on depression, anxiety, stress trust, time management amongst other measures. This data helps managers initiate open conversations on mental health with their team members.

COVID-19-driven demand provides a near-term opportunity

The COVID-19 crisis has been detrimental to the psyche of employees across the globe. It is worthwhile noting at this point that ~53% of adults in the US have reported that their mental health has been negatively impacted by the COVID-19 Pandemic[6]. The mental health consequences of this crisis, including suicidal behaviour, are expected to linger on for a long time and peak after

[6] N Panchal, R Kamal, K Orgera, C Cox, R Garfield, L Hamel, C Muñana, P Chidambaram. The Implications of COVID-19 for Mental Health and Substance Use. Coronavirus – Covid 19. On-line Publication, August 2020.

the actual Pandemic period. As a result, the need for mental health and wellness solutions has never been greater.

With mental health in the workplace receiving more emphasis than ever before, Medibio is witnessing heightened interest and demand for ilumen from existing as well as new clients. The Pandemic is expected to have a profound psychological and social effect even on those employees who have not been directly affected by business closures and restructuring. With deep experience in mental health biometrics, artificial intelligence capabilities and the scalable nature of its technology, Medibio's ilumen is set to benefit from the current crisis.

Poised to foray into consumer mass market

Medibio's mobile app, which will be available on Android and iOS, is targeting the consumer segment to enable assessment of mental health through biometric information obtained from wearable devices (Figure 6).

In January 2021, the company reported that it has commenced initial phase of testing. If the initial testing results turn out to be positive, we believe this would build product visibility in the wider market. Commercial launch in the US market is expected by H2 2021.

Figure 6: Consumer App

Source: Company

Built on a robust clinical foundation

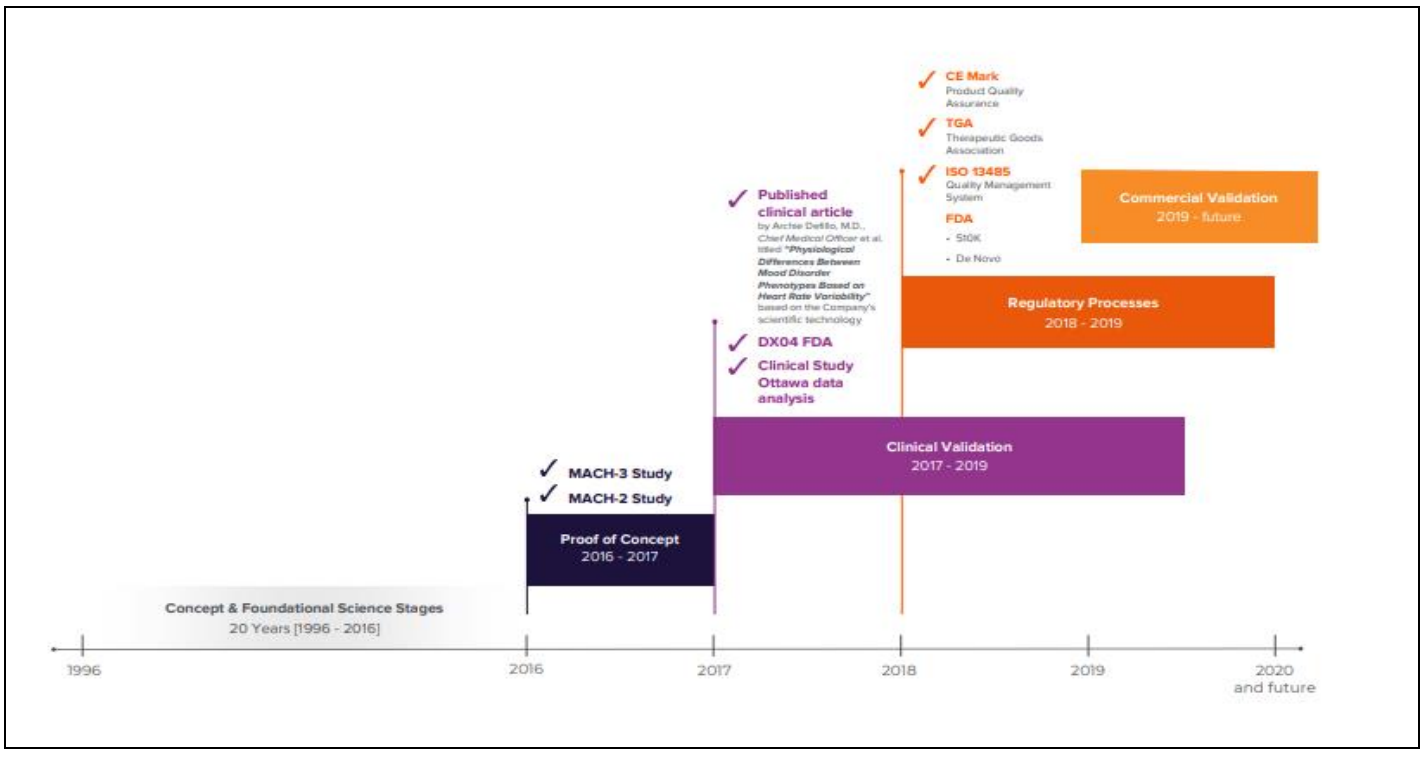
Medibio's technology is based on over 20 years of research initiated at the University of Western Australia

Medibio's technology is based on the correlation between sleep, heart rate, heart rate variability and mental health. Scientific evidence supports observable nighttime patterns in sleep architecture, heart rate, heart rate variability as biomarkers for mental illness. The company's algorithm is based on this solid foundational research initiated in the mid-90s at the University of Western Australia and has since been validated by various pilot and clinical studies.

Proof of concept

In order to identify depressed patients, Medibio conducted MACH-2 and MACH-3 studies in partnership with Johns Hopkins University during 2016–2017 (Figure 7). MACH-2, a retrospective hypothesis study, was conducted on 26 patients and depicted an accuracy of 81% in December 2016. The MACH-3 study, conducted on 60 patients, was designed to be the first prospective depression diagnosis by analysing heart rate variability in a primary care setting. The outcome of the MACH-3 study, announced in August 2017, was an overall accuracy rate of 82%, which exceeded the then prevailing clinical diagnostic performance accuracy range of 30–50%.

Figure 7: Scientific and clinical development process



Source: Company

Notably, the MACH-3 study was designed under more challenging requirements, based on modifications recommended by the FDA during the 2016 pre-submission meeting. The FDA specifically suggested that the control group be representative of patients in a primary care setting and that their age and gender be matched with a major depressive disorder (MDD) cohort.

Significant validation of technology

Validation received through several pilot and clinical studies

Medibio's depression diagnostic has received corroboration through clinical studies undertaken by several global and reputed universities, including Johns Hopkins, Emory and Washington. In June 2016, Medibio partnered with Johns Hopkins University for a sleep-staging observational study using ECG data. With sleep records of 7,500 patients, the company distinguished sleep stages with an accuracy level of 86–95%.

Similarly, in November 2016, Medibio released the outcome of its study conducted in partnership with the University of Ottawa using biomarkers extracted from overnight physiological recordings. The group was larger, with about 889 patients, and study results showed an improved accuracy level of diagnosis at 86% vs. 83% recorded earlier. Higher accuracy was a direct result of the algorithm processing a larger data set.

Further, in September 2018, Medibio released the outcome of the Depression Diagnostic Aide (DX04) study, which was a global, prospective, case-controlled trial designed to accurately identify patients experiencing a major depressive episode. This study, conducted in eight sites across the US and Australia, registered a 70% accuracy level. During the study, 230 patients were clinically diagnosed for neuropsychiatric disorders and assessed by the algorithm. Notably, the clinical study depicted a more than 20% improvement to the current diagnostic standard.

The DX04 clinical study also laid the foundation for research supporting the advancement of Medibio's technology. This research, conducted by Dr. Archie Defillo, Chief Medical Officer of Medibio, concluded that distinct heart rate patterns can clearly differentiate mood and mental disorders. This led to greater awareness about the technology and higher interest among the scientific community.

Medibio received the ISO 13485[7] certification from DQS Med, the regulatory body in Germany, in January 2018. Further, Medibio's Depression Diagnostic Aide (DDA) and Mental Health Monitoring Platform (MHM) were included in the register of Australian Therapeutic Goods Administration (ATGA) in June 2018.

Commercialisation plans on fast track

CE Mark approval granted, US FDA approval underway

Medibio received CE Mark approval for MEBsleep in January 2021

In January 2021, Medibio has been successfully granted with CE Mark approval for its sleep staging software, MEBsleep. This is a big regulatory milestone for the company. It has significant revenue implications as it now enables Medibio to start commercialising its MEBsleep device across the European Economy Community. Furthermore, the CE Mark approval serves as an important validation for the sleeping staging software and paves a strong foundation for the company's development of depressive burden software medical device, MEB-001, of which MEBsleep is a component.

Medibio submitted the 510(k) application to the FDA for MEBsleep in April 2020

In addition, we believe that Medibio's background technology, which has been corroborated by several renowned universities, is also in a strong position to receive the FDA regulatory clearance in the US, one of the biggest markets for its products. Medibio submitted the 510(k) application to the FDA for MEBsleep in April 2020. It received a notification from the agency in August 2020 stating that the application contained all the necessary information required to proceed with a substantive review. In late 2Q21, the

[7] ISO 13485 is recognised internationally as a universal measure of quality and is a critical prerequisite to securing CE Mark and other regulatory certifications.

FDA requested additional data for the approval of MEBsleep, which the company is now working towards.

With regards to MEB-001 – the depressive burden platform – in December 2019, Medibio's SADB feasibility phase study commenced enrollment as part of its process to apply for the FDA's De Novo clearance. While the SADB trial was impacted as sleep clinics suspended operations due to COVID-19 early in the Pandemic, Medibio was able, in October 2020, to ink a clinical trial agreement with MedBridge Healthcare LLC, a provider of sleep laboratory management services in the US, which will help it recover lost ground. MedBridge operates 130 sleep disorder diagnostic centres and performs over 70,000 sleep disorder diagnostic procedures annually. Thus, Medibio hopes to complete the depressive burden trial for the De Novo application by H2 2021, although we note that uncertainty surrounding COVID and lockdowns could cause delay and as such, we suggest having in mind a six-month window to better manage expectations.

Medibio expects to complete the depressive burden trial for the De Novo application by H1 2021

Additionally, the company submitted a request for a Breakthrough Device Designation with the FDA for MEB-001 in October 2020, which coincided with its ongoing clinical trial, as devices requesting a De Novo designation are also eligible for a Breakthrough Device Designation. While the FDA rejected Medibio's request on 3 December 2020, we believe that this decision will not impact the progress of the MEB-001 trials. Further, Medibio has requested a meeting with the FDA to discuss the issues flagged in the notification letter and will accordingly decide on the next steps, to pursue further supervisory review or an appeal, based on the outcome of this meeting.

Gaining traction in the unregulated market

The unregulated market is another lucrative prospect for Medibio, where it can tap the immense opportunities available in the corporate mental health space through its ilumen product. Owing to the COVID-19 Pandemic, mental health in the workplace is receiving more emphasis than ever, and consequently Medibio is witnessing a heightened interest in and demand for ilumen. Moreover, the surge in wearable technology and app-based integration is enabling the company to reach patients directly and easily.

Medibio has made inroads in the corporate market through some key customer wins

Over the past two years, Medibio has been able to gain traction in the corporate mental wellness segment by inking long-term contracts with reputable organisations who have a global workforce. The company will continue to focus on global organisations, which will act as resellers, on a revenue-sharing basis, in order to further support the roll-out of ilumen. We expect more global deals in Medibio's pipeline, driven by referrals from existing clients and growing importance of mental health among employees.

Further, in order to tap into the consumer market directly, Medibio's downloadable mobile app, which is in an advanced development stage, is expected to be launched by H2 2021. This could open up a vast market for Medibio, providing it with an additional revenue stream and enhanced brand recognition.

Mental health concerns are gaining importance worldwide

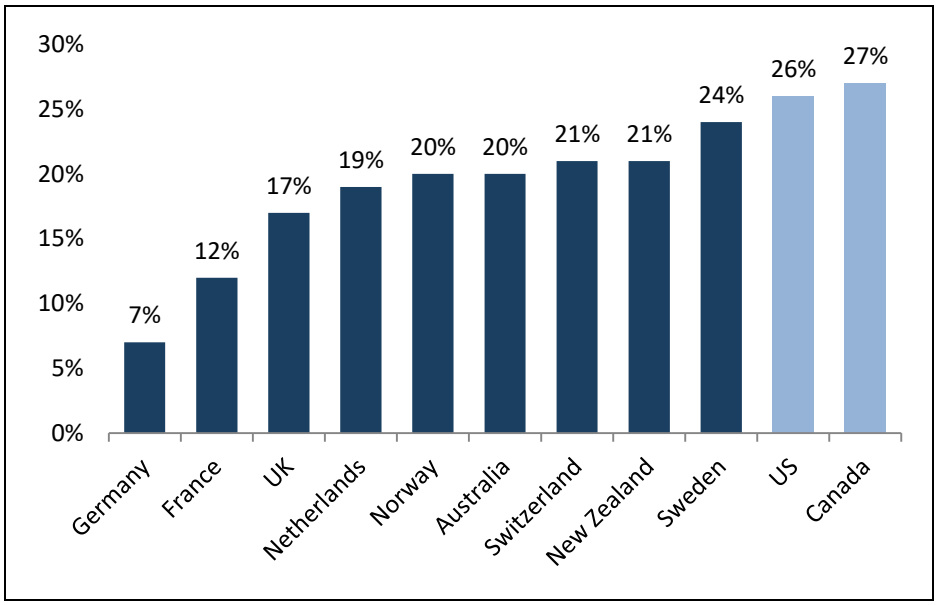
As per a Lancet Commission report on global mental health and sustainable development published in 2018, mental health disorders are on the rise across the globe. The report estimates these rising cases to cost the global economy approximately US$16tn by 2030 compared with the current US$1tn per year[8].

Mental health is accepted as a major issue in developed countries. There are roughly 350 million people suffering from depression in the US and Europe[9]. And this does not include people suffering from high anxiety levels, which represent an additional 7–8% of the total population in the US and Europe. As per the EC, nearly 25% of Europe's population suffers from depression or anxiety[10], resulting in €170bn in costs every year.

Mental illness cases and their costs are on the rise globally

In North America, the picture is equally grim. According to a study conducted by the Commonwealth Fund[11], the US and Canada have the highest rates of mental health diagnosis than other high-income countries (Figure 8). This is partly due to lesser stigma around mental health in North America, due to which people do not hesitate in seeking support.

Figure 8: Self-reported emotional distress rates



Source: 2016 Commonwealth Fund International Health Policy Survey

The economic cost of poor mental health in Canada is at least C$50bn per year, as per a study conducted by Deloitte in 2019[12]. This includes both direct costs related to healthcare, social services and income support, as well as indirect costs, such as absenteeism and employee turnover.

In the Asia Pacific region, mental illness is the second-largest contributor of years lost due to disability (YLDs), as per a 2016 study by EIU[13]. The study estimated that by 2030, YLDs could reduce economic growth in India and

[8] See WHO's 'Mental health in the workplace' at: https://www.who.int/teams/mental-health-and-substance-use/mental-health-in-the-workplace.
[9] See Medibio's Investor Presentation dated 10 June 2020.
[10] See more at https://cordis.europa.eu/project/id/827736.
[11] See '*Mental Health Conditions and Substance Use: Comparing U.S. Needs and Treatment Capacity with Those in Other High-Income Countries*'; at https://www.commonwealthfund.org/publications/issue-briefs/2020/may/mental-health-conditions-substance-use-comparing-us-other-countries.
[12] The '*The ROI in workplace mental health programs: Good for people, good for business*' report by Deloitte published in 2019.
[13] See the '*Mental Health And Integration*' briefing paper published by the Economist Intelligence Unit in 2016.

China by a total of US$11tn. In Australia and New Zealand, the study estimated the total annual cost of mental illness to be 3.5% and 5.0% of the GDP, respectively.

In our view, the growing prevalence and acceptance of mental health issues provide a substantial addressable market to Medibio. As more people seek support, Medibio's products will enable healthcare providers to help their patients efficiently through early and accurate detection of mental illness.

Medibio's solutions can help bypass the stigma around mental illness by providing users personal access to objective diagnosis

Additionally, unlike in North America, mental health is a relatively taboo topic in several Asian cultures. This can lead to delay in detection and treatment of mental illness. We believe Medibio's solutions can help overcome these social and cultural constraints somewhat by allowing individuals personal access to a quick and objective diagnosis of their mental well-being.

Growing concern for mental health in workplaces

Mental health is increasingly gaining attention in workplaces in various industries – from mining and construction to banking and finance, as well as in the field of professional sports. As per the latest report on mental health issued by the Australian government's Productivity Commission in November 2020, mental illness is the second-largest cause of health-related disability in Australia. Similarly, in the US, roughly 1 in 5 adults reported a mental health illness in 2016, as per a report released by the CDC's Workplace Health Program in July 2018[14].

More employers are committing to tackle mental health issues and Medibio's ilumen is well-positioned to aid them

Unchecked mental health issues can cost companies. Mental health issues lead to a number of costs for companies, such as absenteeism, presenteeism (working while unwell) and compensation claims. As per the WHO, depression and anxiety disorders cost the global economy US$1tn each year in lost productivity[15]. Notably, the cost to employers due to mental health concerns has been on the rise recently. For instance, in the UK, the cost of poor employee mental health for companies increased 16% over 2017–2019 to reach £45bn, as per a report published by Deloitte in January 2020[16].

Consequently, many employers are now committing to promote mental well-being among their workforce. As per Australia's Productivity Commission's report, the current programmes in place at workplaces range from being broad-based (i.e., primary interventions) to targeting specific work groups, such as first responders (i.e., secondary interventions). In this context, we believe that Medibio's ilumen offering, which helps measure stress levels in employees, can help organisations efficiently plan the scope of these interventions.

Moreover, the report suggests that early intervention provides significant benefits to companies w.r.t. preserving the mental well-being of their employees. In our view, given that Medibio's product provides early stress indicators by analysing physiological markers of users, it can help in early detection of potential mental health issues.

Study reveals that mental health initiatives at workplace yield positive ROI

Additionally, mental health initiatives have the potential to yield positive return on investment (ROI) for companies. As per a study[17] conducted by Deloitte on seven Canadian companies that implemented mental health initiatives, the companies were able to generate a median yearly ROI of C$1.62 per dollar invested. We believe this could drive adoption of mental

[14] See '*Mental Health In The Workplace*' report by CDC's Workplace Health Program.
[15] See more at https://www.who.int/teams/mental-health-and-substance-use/mental-health-in-the-workplace.
[16] See the '*Mental health and employers – Refreshing the case for investment*' report published by Deloitte in January 2020.
[17] See the '*The ROI in workplace mental health programs: Good for people, good for business*' report by Deloitte published in 2019.

health programmes in workplaces, thereby providing growth opportunities to companies such as Medibio.

Serious treatment gap exists

The increasing prevalence of mental health issues is giving rise to a treatment gap. Lack of access to quality mental healthcare is now a serious global problem. In the US, over 26 million people with mental illness go untreated[18]. This is due to a number of reasons, including the high cost of care, lack of qualified psychiatrists, and disconnect between primary and behavioural care systems. Similarly, in Europe, only 25% of people with mental illness are able to receive any treatment, as per an EIU study[19]. The study further notes that only 10% people affected by mental illness are able to receive 'notionally adequate' care.

In our view, this reinforces the availability of growth opportunities for Medibio. By offering an easily accessible solution to individuals, which provides a quantitative and objective diagnostic, Medibio can help bridge this treatment gap.

Countries are introducing mental health legislations

Mental health issues are gaining attention in legislations of European nations

As per Eurostat, suicide is a major cause of death in Europe, with over 50,000 deaths a year. Notably, 9 of the 10 countries with the highest suicide rates in the world are in Europe. To address this issue, in June 2008, the EC launched the European Pact for Mental Health and Well-being[20].

In addition to this, many European countries have introduced their own policies to tackle this issue. For instance, in Ireland, the Health and Safety Authority offers guidance and feedback to workplaces on workplace stress, employee psychological well-being and critical incident exposure. Similarly, in 2018, the French Strategic Committee on Mental Health and Psychiatry introduced a roadmap[21] for mental health. It includes 37 action points with focus on early identification and management of mental health problems and suicide prevention.

COVID-19 has brought mental health in the limelight

In addition to physical health, the COVID-19 Pandemic is also taking a toll on the mental health of people globally. As per a tracking poll conducted in the US by the Kaiser Family Foundation (KFF) in July 2020, 53% adults reported that worry and stress related to the Pandemic have negatively impacted their mental health. For reference, this rate was 32% in March 2020, when the question was first introduced to the polls.

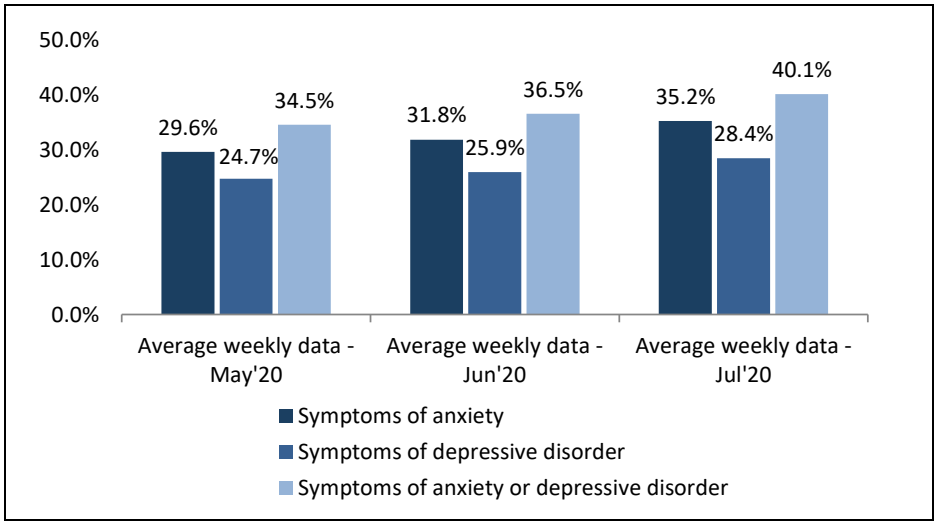
Job-related stress due to the Pandemic has put a heavy strain on mental health of workers

This increase is partly driven by the isolation induced by lockdowns, as well as job losses experienced due to economic distress. Moreover, the stress of having to manage online home-schooling of children along with work is also impacting the mental health of employees. Notably, the mental toll on women in the workplace is ~1.5 times higher than on men, according to McKinsey[22]. McKinsey notes that the stress caused by the Pandemic has led 1 in 4 women in a senior-level position to consider either leaving the workforce or downshift their careers. Further, Latino and Black Americans are reporting higher levels of anxiety and depression than White Americans during the current crisis. These developments pose a serious threat to the diversity of

[18] See '*The Global Mental Health Crisis: 10 Numbers to Note*' by Project Hope; https://www.projecthope.org/the-global-mental-health-crisis-10-numbers-to-note/10/2020/
[19] See more at https://eiuperspectives.economist.com/healthcare/how-countries-are-failing-integrate-people-mental-illness-society
[20] See more at https://www.mentalhealthandwellbeing.eu/the-joint-action.
[21] See the '*Roadmap: Mental Health and Psychiatry, 2018*', https://solidarites-sante.gouv.fr/IMG/pdf/180628_-_dossier_de_presse_-_comite_strategie_sante_mentale.pdf.
[22] See '*Five ways to design a better mental-health future for a stressed-out workforce*' published on 3 November 2020

the current and future workforce, and organisations need to play a proactive role in mitigating this risk.

Figure 9: Rising share of adults reporting symptoms of anxiety or depressive disorder during COVID-19



Source: U.S. Census Bureau, Household Pulse Survey 2020

Coronavirus causes mental illness in survivors

Additionally, as per a study published in the Lancet Psychiatry Journal[23], 20% of the survivors of COVID-19 were diagnosed with a psychiatric disorder within 90 days. Notably, these cases were all first-time diagnosis of anxiety, depression or insomnia in these individuals, indicating a direct correlation between the virus and mental illness.

We believe that as the Pandemic continues to take its toll on the mental health of survivors, and people in isolation and dealing with job stress, the need for mental health solutions is bound to increase. In fact, Medibio's ilumen product has been witnessing a demand uptick from corporates since the onset of the Pandemic and this trend is likely to become stronger in the medium term.

[23] See '*Bidirectional associations between COVID-19 and psychiatric disorder: retrospective cohort studies of 62 354 COVID-19 cases in the USA*' published on 9 November 2020.

Valuation

Using the DCF methodology, we value Medibio at A$0.05 per share base case and A$0.08 per share bull case.

Our revenue model is explained below:

– **Revenue drivers.** Our model breaks down Medibio's group revenue into two units, the regulated business unit and the non-regulated business unit. The regulated unit is further broken down into two sub-units, namely MEBsleep (sleep staging) and MEB-001 (Depressive Burden). As for the non-regulated business unit, we derive its revenue by separately examining the ilumen and Consumer App products. Our key assumptions are shown in Figure 10.

- **Regulated business unit:** We have modelled early revenues to be generated from the commercialisation of MEBsleep in H1 FY22, after which we expect the MEB-001 device to be rolled out and out-licensed to large pharma companies, which effectively incorporates the MEBsleep algorithms. Using a market share-based approach, our expected revenues for both products are driven by the size of the end markets and pricing per test. We use OSA testing volume as a proxy for deriving the size of our target markets. At this stage, we model only the US and European OSA markets. Having obtained the CE Mark approval, we assume Medibio to commence its first sales of MEBsleep in Europe in H1 FY22. We discount our expected revenues at a conservative risk-adjusted rate of 50% to factor in the risks of overcoming the remaining clinical and regulatory hurdles.
- **Non-regulated business unit:**

  On expected sales of ilumen, we anticipate Medibio to continue to execute and sign-up new license contracts with various customers within the Compass Group. According to the company, the initial adopters of ilumen within the Compass Group will be in the UK and Australia. Domestically, following PwC Australia's recent positive experience with ilumen and its contract renewal, we expect Medibio to continue its customer acquisition momentum in Australia. Moreover, given the recent discussions regarding the economic impact of mental illness in Australia[24], we think Medibio's ilumen product is well-positioned to ride this structural tailwind and be potentially rolled out to businesses to help them create a mentally healthy workplace. The resultant strong corporate uptake of ilumen will help drive a material uplift in revenues and cash flows for Medibio over the short to medium term.

  On Consumer App, we model only the US market. Our projected subscriber volume is based on the number of smartphone users in the country, to which we apply a penetration rate to reflect the competitive positioning of the product. We assume first sales of the Consumer App product to commence in H1 FY22.

[24] https://www.news.com.au/lifestyle/health/mental-health/mental-health-hits-australian-economy-by-200bn-every-year/news-story/ac96e5edcd815b59c0ae406f6158b269.

Figure 10: Key revenue model assumptions

Assumptions	Base Case	Bull Case
MEBsleep & MEB-001		
Estimated test volumes for OSA in US (M)	3.9	3.9
Estimated test volumes for OSA in Europe (M)	35.0	35.0
Expected MEB's market share in US (%)	20%	25%
Expected MEB's market share in Europe (%)	20%	25%
Pricing per MEBsleep test (A$)	1,500	1,575
Pricing per MEB-001 test (A$)	450	495
Royalty rate	8%	9%
ilumen		
Estimated pricing per employee (A$)	30	33
Consumer App		
Estimated smartphone users in US (M)	276	276
Growth in smartphone users in US (%)	5%	8%
Long run penetration rate (%)	0.05%	0.10%

Source: Pitt Street Research

Our key DCF assumptions are as follows:

- **Forecast horizon.** Our explicit cash flow horizons for both regulated and non-regulated business units are set at 14 years, after which we assume a terminal growth rate of 2%.
- **Discount rate.** We apply a discount rate of 14.4%, appropriate in our view for a 'Speculative' risk rating[25]. Medibio is still in the infancy stage of revenue generation which we regard as more risky than other more commercialised Life Sciences ventures.
- **Operating margin.** We view Medibio's operating costs as semi-variable, with >40% coming from staff costs. As Medibio begins new product roll-out across its targeted markets, we think its operating losses should gradually improve due to scale efficiency and strong operating leverage. Per our modelling, group EBITDA margin will likely reach c.11.5% in FY25F.
- **Capital.** We assume a $5M in new capital to be raised in FY22 to fund ongoing product development expenditure.
- **Tax rate:** We assume a corporate tax rate of 30%.

Figure 11: DCF valuation summary

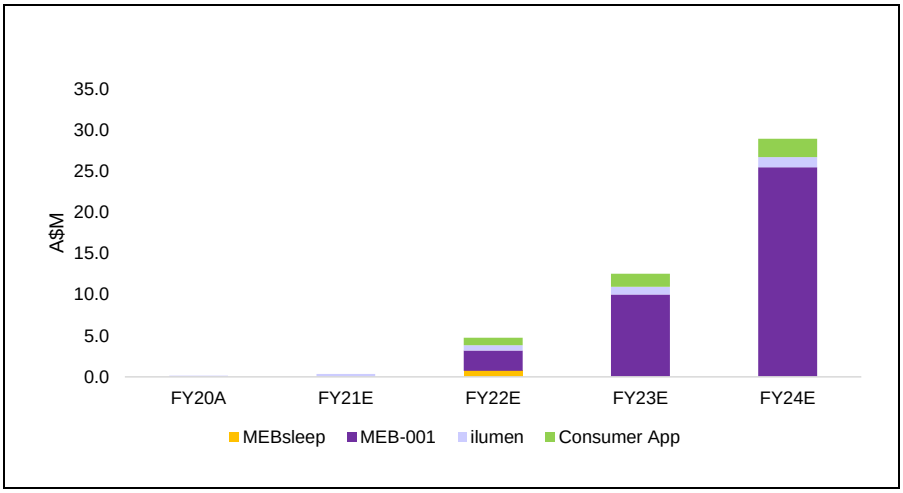
Valuation (A$) - Base Case		Valuation (A$) - Bull Case	
Present value of FCF (m)	77.3	Present value of FCF (m)	134.9
Present value of Terminal FCF	56.7	Present value of Terminal FCF	91.1
Enterprise Value (m)	**133.9**	**Enterprise Value (m)**	**226.0**
Net debt (cash) (m)	(0.7)	Net debt (cash) (m)	(0.7)
Minority interest (m)	-	Minority interest (m)	-
Equity value (m)	134.7	Equity value (m)	226.7
Diluted shares	2,944.3	Diluted shares	2,944.3
Implied price (cents)	**4.57**	**Implied price (cents)**	**7.70**
Current price (cents)	0.70	Current price (cents)	0.70
Upside (%)	*553.4%*	*Upside (%)*	*1000.1%*

Source: Pitt Street Research

[25] For a relevant discount rate, we use varying WACCs depending on the risk for Life Science companies. We start with an RFR of the Australian ten-year bond rate (1.7%) and an ungeared beta of 1.1 but use a variable MRP of 7.5%-11.5% (7.5% for 'medium risk' companies, 9.5% for 'high risk' companies and 11.5% for 'speculative' companies). Ordinarily we regard Life Science companies with existing businesses, or who have enough capital to reach the market with their products, as 'Medium' risk. Companies that have small revenue streams from marketed products but that are still potentially in need of capital are 'High' risk. Everything else is 'Speculative'. We have used a Speculative risk rating for Medibio considering it is still in the infancy stage of revenue generation.

Figure 12 shows our revenue modelling from FY20A to FY25F based on a revenue mix that comprises regulated business revenues (MEBsleep and MEB-001) and non-regulated business revenues (ilumen and Consumer App).

Figure 12: Revenue forecasts by business unit, FY20A to FY25F



Source: Pitt Street Research

Solid leadership team

Medibio's leadership team has significant experience in the fields of healthcare technology as well as mental wellness. The company also rationalised its Board of Directors at the start of this year. The highly experienced and restructured leadership team at Medibio bodes well for the company's prospects in the long run.

The key members of Medibio's management team are as follows:

- **Claude Solitario (Managing Director)** is a founding shareholder and an experienced financial executive. He brings 30 years of experience in the development of various technology-based ventures, with a focus on biotechnology and medical devices.
- **Dr. Archie Defillo (Chief Medical Officer)** has over 25 years of clinical experience in the neurological diseases field. He was previously the lead clinical researcher at the National Brain Aneursym Center in St. Paul, Minnesota (US), and also collaborated with the eminent Australian neurosurgeon, Prof. Dorsch. Dr. Defillo has published over 50 papers on topics including resting heart rate, heart rate variability and broken heart syndrome.
- **Prof. Giampaolo Perna (Clinical Consultant)** is an accomplished researcher and author of many scientific publications. He is the Chairman of the Department of Clinical Neurosciences at Villa San Benedetto Menni Hospital of the Hermanas Hospitalarias (Italy) and is also associated with several academic institutions.
- **Massimiliano Grassi (Head of Artificial Intelligence)** is a data scientist at Medibio and has over 15 years of experience. His focus is on the development of machine learning algorithms for the identification of sleep staging and depressive burden. He is also a clinical psychologist at Villa San Benedetto Menni Hospital.

– **Jennifer Solitario (Senior Vice President, Corporate Health)** possesses over 20 years of experience in the health insurance sector. She previously managed benefits payments of over A$1bn at HBF Health, oversaw the growth of its pharmacy business and developed the company's Community Wellness strategy. Ms Solitario is responsible for the global commercialisation of Medibio's corporate wellness product, ilumen and overseeing the development of the Consumer App.

Medibio's board underwent an overhaul in January 2020, with the number of members reducing from seven to three (Figure 13):

Figure 13: Medibio's current board members

Name	Designation	Affiliations (Current and Past)
Claude Solitario	Managing Director	Invatec Health, Cove Capital
Peter Carlisle	Non-Executive and Lead Independent Director	Octagon
Melanie Leydin	Director and Joint Company Secretary	Leydin Freyer

Source: Company

Claude Solitario was appointed as Managing Director on 9 January 2020. He was previously a Non-Executive Director. He is also one of the major shareholders in the company.

Peter Carlisle was appointed Lead Independent Director on 22 February 2019. He serves as Managing Director of Olympics and Action Sports at Octagon, a global sports marketing agency. He brings over 15 years of experience in the industry and has received numerous awards and recognitions.

Melanie Leydin has over 25 years of experience as an accountant and 15 years as a company secretary. She is a chartered accountant, a registered company auditor and a graduate of Swinburne University. She is also a Principal of the chartered accounting firm, Leydin Freyer.

Medibio also established a **Growth and Advocacy Advisory Board** in 2019, which will be independent of the Board of Directors. Michael Phelps (renowned former competitive swimmer and now an advocate for mental health) and Patrick J Kennedy (former US Representative and currently an active promoter of mental well-being) are the inaugural members of this board, which will be chaired by Peter Carlisle. This body will work closely with Peter Carlisle and the company's management team to identify strategic opportunities to leverage the expertise and network of Michael Phelps and Patrick Kennedy.

Appendix I – Major shareholders

The company has two major shareholders:

– Fidelity International Ltd (6.8%).
– Rookharp Capital Pty Ltd (5.0%).

The company's Managing Director, Claude Solitario, owns ~4.0% stake.

Appendix II – Capital structure

As of 18 May 2021	In million	% of fully diluted	Note
Ordinary fully paid shares	1,795.1	61.0%	
Options	1,149.2	39.0%	Listed and unlisted options expiring at various dates during 2021-2025
Fully diluted shares	**2,944.3**		

Source: Company

Appendix III – IP position

US 10,638,965 *Method and system for monitoring stress conditions,* priority date 15 June 2015, invented by Matthew Flax, Aaron Wong, Michael Player, Todd Jolly and Hans Stampfer.

– The patent discloses a method for assessing a stress condition of a patient and includes recording the patient's heartbeat over a span of time – starting from the pre-sleep period, the sleep period (with the sleep onset time and sleep conclusion time noted) and then the post-sleep period. This data is then compared with historical data from a database of heartbeat records belonging to patients experiencing varied amounts of stress levels and documented by medical experts. The historical data is also used to train a computational model for obtaining a relationship between stress condition and heart rate characteristics. The patient's stress condition is determined based on the comparison between the heartbeat records and a metric computed by the model. Examples of the metric include a mean awake heart rate; ratio between mean awake and mean asleep heart rates; slope of heart rate during the first half of the sleep period; and slope of heart rate in the second half of the sleep period.
– Applications for the patent were filed in Australia, the US, Canada, China, Israel, Japan, Argentina and Europe, and has been granted in the US.
– The US patent is expected to expire in 2037.

US 10,039,485 *Method and system for assessing mental state,* priority date 15 June 2015, invented by Matthew Flax, Aaron Wong, Michael Player, Todd Jolly and Hans Stampfer.

– The patent discloses a method for assessing the mental state (such as a depressive or anxiety-related disorder) of a patient and includes recording the patient's heartbeat over a span of time – starting from the pre-sleep period, the sleep period (with the sleep onset time and sleep conclusion time noted) and then the post-sleep period. This data is then compared with historical data from a database of heartbeat records

belonging to patients experiencing varied amounts of stress levels and documented by medical experts. The patient's mental state is determined based on the comparison between the heartbeat records and a metric computed by the model.

- Applications for the patent were filed in Australia, the US, Canada, China, Israel, Japan, Argentina and Europe, and has been granted in the US.
- The US patent is expected to expire in 2036.

US 2020/0205709 A1 *Mental state indicator,* priority date 11 June 2018, invented by Yashar Behzadi, Nathan Kowahl, Matthew Wescott, Nick Hughes and Sangyeop Lee.

- The patent discloses a system for generating a mental state indicator of a patient that measures the heart rate of the patient during sleep and analyses the data in various sleep segments – such as some minutes preceding sleep onset, some minutes following sleep onset, first half of the sleep episode, second half of the sleep episode and some minutes prior to waking. The system determines a metric based on this analysis. The metric can be a heart rate statistic (such as a mean, a median, an average, a variance, a skew, a kurtosis, a percentile and a cumulative distribution function), a heart rate spectral power metric indicative of a spectral power in various frequency band groups (such as an ultra-low frequency less than ~0.003 Hz; a very low frequency between ~0.003 Hz and ~0.04 Hz; a low frequency between ~0.04 Hz and ~0.15 Hz; and a high frequency between ~0.15 Hz and ~0.4 Hz) and a heart rate variability metric (e.g., a multi-scale entropy, standard deviation of average pulse intervals and square root of the mean of the squares of differences between adjacent pulse intervals). The determined metric is used to predict the mental state of the patient using a computational model based on the relationship between different mental states and the metrics. The computational model is obtained by applying machine learning to reference metrics derived from heart rates measured for reference patients.
- Applications for the patent were filed in Australia and the US; other than that a WIPO application has also been filed.
- The patent is yet to be granted.

WO 2019/075522 A1 *Risk indicator,* priority date 19 October 2017, invented by Yashar Behzadi, Nathan Kowahl and Sangyeop Lee.

- The patent discloses a system, to determine the risk for a patient suffering from an adverse mental state, by measuring data indicative of heart activity of the patient. Heart activity is analysed to determine a metric. The determined metric is used to predict the risk of adverse mental state in a patient using a computational model based on the relationship between different mental states and the metrics.
- A WIPO application has been filed to date.

WO 2019/075520 A1 *Breathing state indicator,* priority date 18 October 2017, invented by Yashar Behzadi, Nathan Kowahl and Sangyeop Lee.

- The patent discloses a system for determining a breathing disorder in a patient that measures the heart rate of a patient during sleep and analyses the data in various sleep segments – such as some minutes preceding sleep onset, some minutes following sleep onset, first half of

the sleep episode, second half of the sleep episode and some minutes prior to waking. The system determines a metric based on this analysis. The determined metric is used to predict the breathing disorder in the patient using a computational model based on the relationship between different breathing disorders and the metrics.

– A WIPO application has been filed to date.

WO 2019/014717 A1 *Medication monitoring system,* priority date 19 July 2017, invented by Yashar Behzadi and Nathan Kowahl.

– The patent discloses a system, to determine the effectiveness of a medication used for treating a mental state of a patient, measures the patient's heart rate during sleep and analyses the data in various sleep segments – such as some minutes preceding sleep onset, some minutes following sleep onset, first half of the sleep episode, second half of the sleep episode and some minutes prior to waking. The system determines a metric based on this analysis. The determined metric is used to predict the effectiveness of the medication on the patient using a computational model based on the relationship between different mental states, medications administered and the metrics.

– A WIPO application has been filed to date.

Appendix IV – Papers relevant to Medibio

Defillo et. al (2018), *Physiological Differences between Mood Disorder Phenotypes Based on Heart Rate Variability.* EC Neurology, Volume 10, Issue 8.

– The paper pertains to a study conducted to understand the accuracy of heart rate variability analysis as a diagnosis of various psychiatric conditions. During the study, a retrospective analysis was done on 24-hour heart rate means and variabilities (standard deviations) of 301 consecutive patients with the diagnosis of either normal, anxiety, depression or mixed. Mean heart rates of the diagnostic groups were compared simultaneously with those of the normal cohort. It was found that the mean heart rates were significantly lower in the normal group than in the groups of patients suffering from mental illness. Standard deviations of the heart rates appear to distinguish groups only by night-time variation, which is significantly less in the depressed patients than in the normal patients or those with anxiety. It was concluded that the accuracy of psychiatric diagnosis can be significantly improved through the use of these distinct patterns of mean heart rate and heart rate variability.

Saad et. al (2019), *Using heart rate profiles during sleep as a biomarker of depression.* BMC Psychiatry, Volume 19, Page 168.

– The paper pertains to a study assessing the validity of an algorithm that uses patterns of heart rate changes during sleep to differentiate between individuals with depression and healthy controls. A heart rate profiling algorithm was modelled using machine learning and trained using polysomnograms of 1,203 patients, including those suffering from depression, those seeking treatment from a sleep clinic for abnormalities (such as insomnia, excessive daytime fatigue and sleep-related breathing disturbances) and the remaining with completely healthy mental controls. The final algorithm was tested on a distinct sample of 174

patients to categorise each patient as depressed or not depressed. The resulting categorisation was compared with medical record diagnoses. It was found that the algorithm had an overall classification accuracy of 79.9% and was highly sensitive across subgroups stratified by age, sex, depression severity, comorbid psychiatric illness, cardiovascular disease and smoking status. It was concluded that sleep-deprived heart rate patterns could act as an objective biomarker of depression, especially when it co-occurs with sleep disturbances, and may serve as a complementary diagnostic tool.

Defillo et. al (2019), *Heart rate variability: Can it serve as a marker of mental health resilience.* J Affect Disord, Volume 263, Pages 754–761.

– The paper reviews heart rate variability as a biomarker of mental health resilience. The method focussed on the relationship between heart rate variability (as measured through decomposition of RR intervals from an electrocardiogram) and responses to laboratory stressors in individuals without medical and psychiatric diseases. It was found that high vagally mediated heart rate variability before and/or during stressful laboratory tasks was associated with enhanced cognitive resilience, appropriate emotional regulation during emotional tasks and better modulation of cortisol, cardiovascular and inflammatory responses during psychosocial/mental tasks. It was concluded that vagally mediated heart rate variability may serve as an index of an individual's flexibility and adaptability to stressors. This supports the idea of heart rate variability as a plausible, non-invasive and easily applicable biomarker of mental health resilience.

Stratton et. al (2017), *Effectiveness of eHealth interventions for reducing mental health conditions in employees: A systematic review and meta-analysis.* PLoS One, Volume 12, Issue 12, Pages e189904.

– The paper details a review and meta-analysis of the effectiveness and relative efficacy of different types of eHealth interventions for employees. Systematic searches were conducted for articles, published from 1975 to 17 November 2016, detailing trials of eHealth mental health interventions for employees. The quality and bias of all identified studies were assessed. Means and standard deviations of the effects of these interventions were extracted and meta-analysed. The results suggested a small positive effect at both the post intervention and follow-up stages. Differential short-term effects were observed between the intervention types, wherein mindfulness-based interventions showed larger effects than CBT-based and stress-management-based interventions. It was concluded that eHealth interventions delivered to employees may reduce mental health and stress symptoms post intervention; however, the benefits seemed to be reducing after follow-ups. It was also concluded that not all such interventions are equal, many lack evidence and achieving the best outcomes depends on providing the right type of intervention to the correct population.

Goldstein et. al (2020), *Call to action regarding the vascular-bipolar link: A report from the Vascular Task Force of the International Society for Bipolar Disorders.* Bipolar Disord, Volume 22, Issue 5, Pages 440–460.

– The article comments on the association between bipolar disorder and vascular diseases. Based on a review of the literature published in the

past, the authors found that the association is high in magnitude, consistent across studies and independent of confounding variables. The vascular–bipolar link is multifactorial and difficult to study given the latency between the onset of bipolar disorder, often in adolescence or early adulthood, and subsequent vascular disease – which usually occurs decades later. As a result, studies have often focussed on risk factors for vascular disease or intermediate phenotypes, such as structural and functional vascular imaging measures. There is interest in identifying the most relevant mediators of this relationship, including lifestyle, medications and systemic biological mediators (e.g., inflammation). It is concluded that there is paucity of treatment studies that deliberately engage these mediators, and to date no treatment studies have focussed on engaging vascular imaging targets. It was also concluded that further research holds promise for gleaning insights regarding the underlying causes of bipolar disorder, identifying novel treatment approaches and mitigating disparities in cardiovascular outcomes for people with bipolar disorder.

Baglioni et. al (2016), *Sleep and mental disorders: A meta-analysis of polysomnographic research.* Psychol Bull, Volume 142, Issue 9, Pages 969–990.

– The paper describes a meta-analysis aimed at determining the PSG characteristics of several mental disorders. As a part of the process, relevant studies were searched. Controlled PSG studies evaluating sleep in affective, anxiety, eating, pervasive developmental, and borderline and antisocial personality disorders; attention deficit hyperactivity disorder (ADHD); and schizophrenia were included. PSG variables of sleep continuity, depth and architecture, as well as rapid eye movement (REM) were considered. Sources of variability – such as sex, age and mental disorder comorbidity – were evaluated in subgroup analyses. Sleep alterations were evidenced in all disorders, with the exception of ADHD and seasonal affective disorders. It was found that sleep continuity problems featured in most mental disorders. Sleep depth and REM pressure alterations were associated with affective, anxiety, autism and schizophrenia. Comorbidity was associated with enhanced REM sleep pressure and increased inhibition of sleep depth. It was concluded that sleep continuity disturbances imply a transdiagnostic imbalance in the arousal system that represents a basic dimension of mental health, and that sleep depth and REM variables may play a key role in psychiatric comorbidity processes.

Appendix V – Companies comparable to Medibio

We have shortlisted the following comparable companies in the mental health space, which have market capitalisation below US$500m and operate in developed countries:

Company	Location	Code	Market Cap. (US$m)	Website
Monsenso A/S	Denmark	CPSE: MONSO	27.6	www.monsenso.com
Cambridge Cognition Holdings	Cambridge, UK	AIM: COG	23.8	www.cambridgecognition.com
Global Health Ltd	Australia	ASX: GLH	14.8	www.global-health.com
Kontigo Care AB	Sweden	OM: KONT	11.2	www.kontigocare.com
EHAVE Inc.	Florida, US	OTCPK: EHVVF	1.27	www.ehave.com
Medibio	Australia	ASX: MEB	10.2	www.medibio.com.au

Source: Pitt Street Research, S&P Capital IQ

Monsenso A/S. It offers cloud-based solutions for the treatment of patients with mental disorders. Through its smartphone app and wearable technology, it helps patients with self-assessment, data collection, trigger/warning signs, medication compliance, visualisation and motivational feedback.

Cambridge Cognition Holdings. This is a neuroscience technology company optimising the assessment of cognition for better brain health. It provides scientifically validated digital health tools that help capture and analyse data related to neurological functions.

Global Health Ltd. This company develops and sells application software for the healthcare sector. It provides comprehensive mental health software that helps psychologists and psychiatrists with client assessment, data records, risk identification, reporting, appointment, reminders and billing.

Kontigo Care AB. It provides artificial intelligence-based healthcare solutions for addiction treatment. Its Previct tool enables real-time analysis and can help detect relapses at early stages.

EHAVE Inc. This Canada-based firm develops medical cannabis and has a mental health data platform. It offers rehabilitation programmes and dashboards, which compile patient data for proper assessment.

Appendix VI – Analyst Qualifications

Stuart Roberts, lead analyst on this report, has been an equities analyst since 2002.

- Stuart obtained a Master of Applied Finance and Investment from the Securities Institute of Australia in 2002. Previously, from the Securities Institute of Australia, he obtained a Certificate of Financial Markets (1994) and a Graduate Diploma in Finance and Investment (1999).
- Stuart joined Southern Cross Equities as an equities analyst in April 2001. From February 2002 to July 2013, his research speciality at Southern Cross Equities and its acquirer, Bell Potter Securities, was Healthcare and Biotechnology. During this time, he covered a variety of established healthcare companies, such as CSL, Cochlear and Resmed, as well as numerous emerging companies. Stuart was a Healthcare and Biotechnology analyst at Baillieu Holst from October 2013 to January 2015.
- After 15 months over 2015–2016 doing Investor Relations for two ASX-listed cancer drug developers, Stuart founded NDF Research in May 2016 to provide issuer-sponsored equity research on ASX-listed Life Sciences companies.
- In July 2016, with Marc Kennis, Stuart co-founded Pitt Street Research Pty Ltd, which provides issuer-sponsored research on ASX-listed companies across the entire market, including Life Sciences companies.
- Since 2018, Stuart has led Pitt Street Research's Resources Sector franchise, spearheading research on both mining and energy companies.

Cheng Ge is an equities research analyst at Pitt Street Research.

- Cheng obtained a B. Com in Finance and LL. B from the University of New South Wales, in 2013, and has passed all three levels of the CFA Program.
- Before joining Pitt Street Research, he has worked for several financial services firms in Sydney, where his focus was on financial advice.
- He joined Pitt Street Research in January 2020.

Profit & Loss (A$m)	FY19A	FY20A	FY21E	FY22E	FY23E	FY24E	FY25E
Group revenue	**0.4**	**0.1**	**0.3**	**4.7**	**12.5**	**28.9**	**56.3**
Operating expenses	(6.4)	(3.5)	(2.1)	(5.9)	(12.2)	(26.4)	(49.6)
EBITDA	**(6.1)**	**(3.3)**	**(1.8)**	**(1.2)**	**0.3**	**2.5**	**6.7**
Depn & Amort	-	(0.1)	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)
EBIT	**(6.1)**	**(3.5)**	**(2.1)**	**(1.4)**	**0.1**	**2.2**	**6.5**
Net Interest	0.0	(0.0)	(0.0)	(0.0)	0.0	0.0	0.0
Profit before tax (before exceptionals)	**(6.0)**	**(3.5)**	**(2.1)**	**(1.4)**	**0.1**	**2.3**	**6.5**
Tax expense	-	-	-	-	-	-	-
Abnormals + Minorities	(0.5)	(0.2)	-	-	-	-	-
NPAT (underlying)	**(5.5)**	**(3.3)**	**(2.1)**	**(1.4)**	**0.1**	**2.3**	**6.5**
NPAT (reported)	**(6.6)**	**(3.7)**	**(2.1)**	**(1.4)**	**0.1**	**2.3**	**6.5**

Cash Flow (A$m)	FY19A	FY20A	FY21E	FY22E	FY23E	FY24E	FY25E
Profit after tax	(6.6)	(3.9)	(2.1)	(1.4)	0.1	2.3	6.5
D&A	-	0.1	0.3	0.3	0.3	0.3	0.3
Change in trade and other receivables	1.7	(0.0)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)
Change in trade payables	(1.9)	(0.6)	0.5	0.5	0.5	0.5	0.5
Other operating activities	(0.1)	0.8	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)
Operating cashflow	**(6.9)**	**(3.6)**	**(1.4)**	**(0.8)**	**0.7**	**2.9**	**7.1**
Capex	(1.1)	(1.5)	(0.0)	(0.2)	(0.6)	(1.4)	(2.8)
Other investing activities	0.1	0.0	0.0	0.0	0.0	0.0	0.0
Investing cashflow	**(1.1)**	**(1.5)**	**(0.0)**	**(0.2)**	**(0.6)**	**(1.4)**	**(2.8)**
Dividends	-	-	-	-	-	-	-
Equity raised (repurchased)	0.8	4.7	1.5	5.0	-	-	-
Debt drawdown (repaid)	-	-	-	-	-	-	-
Other financing activities	2.3	(0.2)	-	-	-	-	-
Financing cashflow	**3.1**	**4.6**	**1.5**	**5.0**	**-**	**-**	**-**
Net change in cash	**(4.8)**	**(0.5)**	**0.1**	**4.0**	**0.1**	**1.5**	**4.3**
Cash at End Period	1.3	0.8	0.9	4.9	5.0	6.5	10.8
Net Debt (Cash)	1.4	(0.7)	(0.8)	(4.8)	(4.9)	(6.4)	(10.7)

Balance Sheet (A$m)	FY19A	FY20A	FY21E	FY22E	FY23E	FY24E	FY25E
Cash	1.3	0.8	0.9	4.9	5.0	6.5	10.8
Total Assets	13.3	14.0	13.9	18.0	18.6	21.4	28.3
Total Debt	2.8	0.1	0.1	0.1	0.1	0.1	0.1
Shareholders' Funds	8.6	12.6	12.1	15.6	15.7	18.0	24.5

Ratios	FY19A	FY20A	FY21E	FY22E	FY23E	FY24E	FY25E
Net Debt/Equity (%)	-5.8%	-6.8%	-6.8%	-30.8%	-31.3%	-35.6%	-43.9%
Return on Equity (%)	nm	nm	nm	nm	0.4%	12.6%	26.5%

General advice warning, Disclaimer & Disclosures

Terms & Conditions

The information contained herein ("Content") has been prepared and issued by Pitt Street Research Pty Ltd ACN 626365615 ("Pitt Street Research"), an Authorised Representative (no: 1265112) of BR Securities Australia Pty Ltd. ABN 92 168 734 530, AFSL 456663. All intellectual property relating to the Content vests with Pitt Street Research unless otherwise noted.

Disclaimer

Pitt Street Research provides this financial advice as an honest and reasonable opinion held at a point in time about an investment's risk profile and merit and the information is provided by the Pitt Street Research in good faith. The views of the adviser(s) do not necessarily reflect the views of the AFS Licensee. Pitt Street Research has no obligation to update the opinion unless Pitt Street Research is currently contracted to provide such an updated opinion. Pitt Street Research does not warrant the accuracy of any information it sources from others. All statements as to future matters are not guaranteed to be accurate and any statements as to past performance do not represent future performance.

Assessment of risk can be subjective. Portfolios of equity investments need to be well diversified and the risk appropriate for the investor. Equity investments in a listed or unlisted company yet to achieve a profit or with an equity value less than $50 million should collectively be a small component of an individual investor's equity portfolio, with smaller individual investment sizes than otherwise. Investors are responsible for their own investment decisions, unless a contract stipulates otherwise.

Pitt Street Research does not stand behind the capital value or performance of any investment. Subject to any terms implied by law and which cannot be excluded, Pitt Street Research shall not be liable for any errors, omissions, defects or misrepresentations in the information (including by reasons of negligence, negligent misstatement or otherwise) or for any loss or damage (whether direct or indirect) suffered by persons who use or rely on the information. If any law prohibits the exclusion of such liability, Pitt Street Research limits its liability to the re-supply of the Information, provided that such limitation is permitted by law and is fair and reasonable.

General advice warning

The Content has been prepared for general information purposes only and is not (and cannot be construed or relied upon as) personal advice nor as an offer to buy/sell/subscribe to any of the financial products mentioned herein. No investment objectives, financial circumstances or needs of any individual have been taken into consideration in the preparation of the Content.

Financial products are complex, entail risk of loss, may rise and fall, and are impacted by a range of market and economic factors, and you should always obtain professional advice to ensure trading or investing in such products is suitable for your circumstances, and ensure you obtain, read and understand any applicable offer document.

Disclosures

Pitt Street Research has been commissioned to prepare the Content. From time to time, Pitt Street Research representatives or associates may hold interests, transact or hold directorships in, or perform paid services for, companies mentioned herein. Pitt Street Research and its associates, officers, directors and employees, may, from time to time hold securities in the companies referred to herein and may trade in those securities as principal, and in a manner which may be contrary to recommendations mentioned in this document.

Pitt Street Research receives fees from the company referred to in this document, for research services and other financial services or advice we may provide to that company. The analyst has received assistance from the company in preparing this document. The company has provided the analyst with communication with senior management and information on the company and industry. As part of due diligence, the analyst has independently and critically reviewed the assistance and information provided by the company to form the opinions expressed in the report. Diligent care has been taken by the analyst to maintain an honest and fair objectivity in writing this report and making the recommendation. Where Pitt Street Research has been commissioned to prepare Content and receives fees for its preparation, please note that NO part of the fee, compensation or employee remuneration paid will either directly or indirectly impact the Content provided.