ASX Announcement
Medibio Limited – 12 November 2020

CHAIRMAN'S ADDRESS
ANNUAL GENERAL MEETING
12TH NOVEMBER 2020

Ladies and gentlemen, it is with great pride that I address you here today as Managing Director and major shareholder of Medibio Limited, a company that I co-founded many years ago.

I say with great pride because I believe we are on the threshold of something quite unique and significant in the area of mental health.

Unique because we are applying cutting edge technology in an area of medicine that has been devoid of technological development despite such advances in almost all other areas of medicine.

Significant because the diagnosis of mental illness, depression in particular, has relied solely on subjective measures since the first publication of the Diagnostic and Statistical Manual, DSM1, in 1952, some 68 years ago.

This is about to change.

In 2013 the National Institute of Mental Health in the USA stated, and I quote:

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

There has never been a greater need for an objective, data-driven approach to assist the clinician in his or her diagnosis of depression.

Medibio's regulatory team in Minneapolis and Milan are developing algorithms and a related software platform, collectively known as MEB-001, that aims to do just that; to provide the clinician with an objective, data-driven approach, based on the patient's own biological data, to assist in the diagnosis of depression.

MEB-001 is a medical device consisting of 3 main components:

1. The sleep staging algorithms; overlaid by
2. Resting heart rate and heart rate variability algorithms, that will lead to:
3. The depressive burden analysis.

MEB-001 uses only EEG and ECG from polysomnography data.

Our team in Minneapolis is currently undertaking a clinical trial known as the "Sleep Analysis of Depressive Burden".

The aim of trial is to objectively identify depressive burden in patients with sleep disturbance who undergo a study in a sleep clinic.

During the depressive burden trial, data analysis will be performed after 50-70 patients and compared to clinical observations with reference to the BDI-II (Becks Depression Inventory) and PHQ-9 (Patient Health Questionnaire 9).

The result of this analysis will be used for a pre-submission meeting with the FDA, which we hope to schedule next month.

The pre-submission meeting is to agree on endpoints of the trial and prepare for a larger "Pivotal Study", which will then form the basis for our De Novo submission.

We anticipate that the pivotal study will require approximately 200-300 patients.

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

Commercially, our aim is to have a depressive burden report attached to every Obstructive Sleep Apnea report.

Our report will allow the physician to better direct the treatment paths for those patients presenting higher on the diagnostic scale for depressive burden.

It is estimated that there are approximately 3.5 million Obstructive Sleep Apnea tests ordered each year in the USA alone. At an average CPT (Current Procedural Terminology) price of US$79 per test, revenue potential in this market one segment alone is US$276 million per annum.

Ladies and gentlemen, the events of COVID-19 have only heightened what was already a major problem in our society.

Mental health consequences of the COVID-19 crisis including suicidal behaviour are likely to be present for a long time and peak later than the actual pandemic.

In response to these circumstances, on the 30th September, we submitted a request that MEB-001 be given "Breakthrough Device Designation" by the FDA.

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

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

We believe that MEB-001 qualifies in more than one of these criteria and are hopeful of receiving breakthrough designation.

The benefits of Breakthrough Device Designation are that it will a) fast-tracks the FDA's review process; and b) provides us with additional opportunities to interact with FDA senior management.

The FDA has advised that they will provide a final decision to grant or deny our request within 60 calendar days of the receiving our submission, which we hope to be the end of November or early December.

It is important to note however, that the depressive burden trial will continue regardless of whether we secure Breakthrough Device Designation.

A signpost on the way to developing MEB-001, has been the development of our sleep staging algorithms, known as MEBsleep.

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

The primary purpose of MEBsleep is the identification of sleep stages, which as mentioned earlier, is an essential part of MEB-001.

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

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

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

We now await their determination and remain optimistic of clearance, as we do for CE Mark in Europe.

Again, it is important to note to note that FDA clearance of MEBsleep is not required for MEB-001.

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

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

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

Their expertise and reputation in sleep medicine in the United States is exemplary, and the size of their operations will greatly assist patient recruitment for our depressive burden trial.

I cannot understate the importance of our collaboration with MedBridge.

It will not only provide us access to many sleep clinics to facilitate patient recruitment; but they will also provide valuable market intelligence for our regulated products MEBsleep and MEB-001 during their development.

I would like to quote Mr. John Mathias, Chief Development Officer of MedBridge who said:

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

He also said:

"As the leading sleep management service provider in the US, we are excited about the potential of Medibio's technology and its clinical applications".

I look forward to developing a mutually profitable relationship with MedBridge.

At this juncture, I would like to comment on the work of our regulatory team in Minneapolis, which includes admin and HR.

They have worked diligently and tirelessly through the disruption of a company-wide restructure, followed shortly thereafter by the disruptions caused by COVID-19.

For those of you who may not be aware, our team in Minneapolis works very closely with the medical team at the Humanitas University in Milan. Indeed our Head of Artificial Intelligence resides and works in Milan.

As I'm sure you are aware, both Minneapolis and Milan were hit very hard by COVID-19. Travel restrictions and home quarantining added layers of difficulty in maintaining cohesion during our research and development programs.

Therefore I would like to highly commend our teams in Minneapolis and Milan and thank them for their tireless work and dedication, in very trying circumstances.

I will now turn to our non-regulated business unit.

As I'm sure many of you are aware, Medibio has developed a corporate mental health product known as ilumen.

Ilumen is delivered via an app or website and targeted at corporations (i.e. employers).

ilumen offers employers a dashboard of aggregated, de-identified data in real-time, so they can better support and manage the mental well-being of their workforce.

Employers are becoming increasingly aware of the cost of mental health. In response, many of them have implemented programs to assist the mental wellbeing of their employees.

However, until now, they have been unable to assess the impact of those mental health programs.

Ilumen provides employers with data so they can measure the impact of the programs that they implement.

Employers can now know if programs they have implemented, resonated with their employees and whether those programs have improved the mental well-being of their workforce.

For the employee, ilumen combines psychometric evaluations with the ability to track biometrics such as heart rate, sleep quality and activity levels using a Garmin or Fitbit wearable device.

ilumen offers the employee a mental well-being "snapshot" they can use to make improvements over time; as well as providing them with tools to better cope with managing life at work.

In October 2019 we announced the signing of our first annual license with PwC in Australia.

It is particularly pleasing to report that due to the positive experience with ilumen, PwC has recently renewed its license for a second year.

In recent months we have signed two additional annual licences, both with very good user feedback.

In July 2019 we announced the commencement of what would become four pilot programs for Compass Group Plc in London.

Compass is a multinational corporation providing contract food and related support services globally across five broad industry groups including Business & Industry, Defense, Offshore & Remote, Education and Healthcare, Sports & Leisure.

The Compass group of companies operates in 45 countries and collectively employs approximately 600,000 people, with revenue group-wide of approximately £23Billion (I note that these are pre-Covid figures).

Some Compass group customers include Google, Coca Cola, Chevron, Shell, American Express, HSBC, Bank of America, Nike and UK Defense to name a few.

It was pleasing to learn that following a world-wide search for a mental health tool by Compass Head Office in London, they chose ilumen as their preferred mental health product.

At this point, I would like to quote Mr. Federico Tonetti, Global Safety & Sustainability Director at Compass Group Plc in London.

It is a rather long quote but I think it sums up beautifully the value of ilumen.

He said:

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

With that background, I am pleased to announce today that Compass Group Plc and Medibio are in the final stages of negotiations in relation to a 3 year Master Software License and Referral Agreement for ilumen, with an automatic renewal for a further 2 years.

The commercial terms of the agreement have been agreed by the parties, and the document is being finalized by Compass Group's and Medibio's lawyers.

Once that agreement is signed, Compass Group companies around the world will be able to place orders for ilumen for their staff on agreed terms, and at agreed prices, without the need for Head Office approval.

The agreement will also grant Compass Group companies around the world the right to introduce ilumen to their client companies.

In return Medibio will earn annual license fees from every Compass company and every Compass client company around the world, that implements ilumen.

The annual license fee will be calculated at a rate per-employee, per-annum, based on the entire worldwide Compass Group workforce enrolled in the program, regardless of the actual employee participation rate.

The agreement provides for a sliding scale to encourage volume, and a rebate model for early adopters as the group-wide number of enrolled employees increases.

Given the global reach of the Compass group of companies; and the number, size and calibre of the companies that they service, this will be a significant agreement indeed.

Based on our pilot program experience and discussions to date, we expect the earliest adopters of ilumen within the Compass group will be in the UK and Canada.

Both of those licenses would be material in terms of revenue.

In Australia, the initial focus will be on Compass client companies, particularly in the Resources, Offshore & Remote sectors.

We are very excited at the prospect of working so closely with Compass.

There is much work to be done and we look forward to a long and mutually rewarding relationship with them.

Although Compass has been a **major** focus for us, they are by no means the **only** focus of our attention.

The global pandemic has brought mental health to the forefront of everyone's mind.

However it has presented challenges from a sales & marketing perspective given that many organizations have had to reduce budgets and headcount.

Introducing a new and innovative technology is difficult at the best of times. The current environment, with particular reference to lockdowns, has added additional challenges, despite the emphasis on mental health.

Nevertheless, we have had discussions with many potential client corporations, and we are hopeful that with Victoria now opening for business and the West Australian borders opening, albeit slowly, we will be able to better progress these discussions and increase our sales and marketing activities in Australia, in the coming weeks and months.

Certainly, our agreements with PwC, Stantec (as announced earlier this year) and now Compass, we now have quality reference points for discussions with other potential client companies.

In July this year I took great pleasure in commissioning the development of a Consumer App, which is now well advanced.

The App functionalities and design features have been determined.

The biometric functionality, which will be our unique selling proposition, is currently being developed by Medibio's regulatory team.

There are many stress apps in the market that focus on **treating** stress. There are few that focus on **measuring** stress; and of those few, **none** have a biometric functionality.

The biometric assessment will be supplemented by a psychometric assessment, that the user may also undertake in combination with the biometric test, or in isolation if the user does not have a wearable device.

The psychometric assessment is being developed by our team at Humanitas University in Milan.

The Consumer App will be available on Android or IOS to any individual that has an interest in assessing and monitoring their levels of stress.

Of course, Medibio can offer these functionalities only as a result of our deep experience in mental health biometrics, AI capabilities and importantly, our intellectual property supported by our patents.

The coronavirus pandemic is having a profound psychological and social effect that will probably persist for months, if not years to come.

The time has never been better for Medibio to release a stress app with its unique selling proposition of a duel biometric and psychometric assessment.

The commercial terms of the app are yet to be determined, suffice to say that we envisage a free download followed by paid upgrades depending on functionality.

Estimates of how many android and OIS users there are in the USA vary, suffice to say it is in the multi millions and whilst download activity is difficult to predict, we are optimistic of the commercial viability of the Consumer App.

I personally am very excited to be overseeing its development and I look forward to the prototype with the full feature set for presentation at the end of 2020 and the commercial launch in 2021.

As I mentioned earlier, the introduction of a new technology is difficult in the best of times.

Selling and implementing a new technology in an environment of lockdowns, border closures and tightening corporate budgets has made it challenging to say the least, despite the greater emphasis on mental health.

Therefore, I must also highly commend our team here in Australia and thank them for their tireless work and dedication, in very trying circumstances; and may I say, in the case of ilumen, their persistence in an environment where ilumen has not always had the status deserving of it in my view.

Ladies and Gentlemen, the year ahead for Medibio is exciting.

After a few years of stagnation, we can look forward to a period of growth.

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

- Securing the first of many Compass Companies and Compass client companies for ilumen on a global scale.
- We look forward to securing additional ilumen licenses in Australia as borders reopen;
  - All of which of course translate to revenue.
- We look forward to the 510(k) clearance for MEBsleep
  - potentially opening the way to early revenue of a regulated product.
- We look forward to securing Breakthrough Device Designation;
  - Raising the status of our medical device MEB-001 and giving our regulatory team better access to FDA management.
- We look forward to our pre-submission meeting with the FDA to agree on endpoints for our depressive burden trial.
- We look forward to the commercial launch of our Consumer App;
  - Providing us with an additional source of revenue next calendar year; and
- We look forward to completing the depressive burden trial and the De Novo submission for MEB-001, to which we can then lay claim to having developed the world's first objective test for depression.

Our mission is crystal clear.

Our strategy is focused.

Company morale is higher than it has ever been.

We have a highly talented and dedicated team, who have been incentivized via employee options, vesting only if and when certain well defined regulatory and revenue milestones are met.

Expenditure is under control.

Medibio has never been in better shape.

I would like to conclude by thanking all shareholders for your support.

I trust that you will continue your interest in and involvement with Medibio.

That concludes my presentation.

ENDS

This announcement is authorized for release to the market by the Board of Directors of Medibio Limited.

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About Medibio Limited

Medibio (ASX: MEB) (OTCQB: MDBIF) is a mental health technology company pioneering the use of objective measures to aid in the early detection and screening of mental health conditions. Through their Corporate Health product, the Company offers mental well-being solutions for businesses and are also developing products to serve the healthcare provider market. The company was founded in Australia, with offices located in Melbourne (Vic) and Minneapolis (MN). Medibio is listed on the Australian Securities Exchange Ltd and trades on the OTCQB Venture Market. Investors can find additional information on www.otcmarkets.com and www.asx.com.au.

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