

Medibio Limited - 9 December 2019

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## Report to Shareholders on Company Activities and Outlook for 2020

**Melbourne, Australia and Minneapolis, MN – 9 December 2019: Medibio Limited (MEB** or the **Company)**(ASX: MEB)(OTCQB: MDBIF), a health technology company today provides and update on company activities.

Medibio is entering its next phase of development and has a renewed focus on the two key products that it has developed for the mental health and wellness markets. To support this focused effort, the Company has initiated a number of immediate actions.

**Key Points:** 

- Focus on fast-track commercialisation of ilumen<sup>™</sup>, including increased marketing and sales profile
- Building on encouraging corporate response from current ilumen<sup>™</sup> pilots underway
- FDA and 510(k) programs planned for 2020:
  - 1. Clinical Depressive Burden; and
  - 2. Sleep-Staging Analysis
- Substantial cost savings from US operations reduction and relocation
- Management changes to reflect company focus and commitment

#### ILUMEN<sup>™</sup> STRATEGY

Since launching the Company's corporate well-being product, ilumen<sup>™</sup>, in October 2018, we have seen growing interest worldwide in what the product can deliver to both employers and their employees.

As with any new and innovative technology, some organisations have wanted to pilot ilumen<sup>™</sup> to evaluate its benefits before making a long-term commitment. In this calendar year, Medibio has undertaken a number of pilot programs, some of which are ongoing, and has recently converted its first pilot into an annual licence.

These pilots are with significant global corporations who have responded enthusiastically to ilumen<sup>TM</sup>. While participation by employees in the pilot programs is voluntary, participation rates have been as high as 85%, due to the simplicity of the application and the value of the data ilumen<sup>TM</sup> provides to individual employees. These participation rates have exceeded our expectations and indeed the expectations of the employer organisations.

Feedback on the value of real-time de-identified aggregated dashboards that ilumen<sup>™</sup> provides has been most encouraging. The dashboards are the first of their kind from Medibio; our client organisations confirm that the "snapshot", data and insights ilumen<sup>™</sup> provides about the mental well-being of its workforce is unique and unprecedented. With ilumen<sup>™</sup>, organisations now have data and information they can measure, monitor and act upon to help support and improve the mental well-being of their workforce. Over time the results will reduce absenteeism and improved productivity.

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In a world where mental health has become a significant issue for both the employer and the employee, ilumen<sup>TM</sup> is well-placed to achieve a positive and lasting difference. Ilumen<sup>TM</sup> empowers client organisations to be proactive instead of reactive with their workforce.

In short, we are very pleased with the results that we are seeing from the pilots to date, and as a result we look forward to converting these pilots to additional annual licences for ilumen<sup>™</sup>. As we on-board large corporations and further prove the technology in the global marketplace, we will be able to secure licences without pilot programs, significantly shortening the lead time to revenue. In this regard It was particularly pleasing to announce in October of this year the Company's first annual licence agreement for ilumen<sup>™</sup> with PricewaterhouseCoopers.

Due to the early success and the continuing interest in ilumen<sup>™</sup>, Medibio has conducted a wide-ranging analysis of ilumen's commercial opportunities. Parallel to that, the Company has undertaken a comprehensive review of our internal operations in order to identify cost savings that can, in whole or in part, be applied to the commercialisation of ilumen<sup>™</sup>.

As a result of these examinations, the Company will relocate its corporate, financial and administrative activities from the US to Australia, effective as of 31 December 2019. This will include the development and global commercialisation activities for ilumen<sup>™</sup>. This change will involve a significant downsizing of the Minneapolis office, which will focus on and continue its important development of our regulated products and related FDA program. This will result in substantial cost savings, much of which will be applied to the commercialisation of ilumen<sup>™</sup> and to support revenue generation as quickly as possible.

As a part of this plan, the Company will step up its marketing and sales efforts for ilumen<sup>™</sup> on the east coast of Australia and the US early in the new calendar year. This reprioritising of expenditures to support the commercialisation of ilumen<sup>™</sup> will slow the progress of the De Novo program. However, the Board is of the view that priority must be given to revenue-generating activities at this time.

### FDA PATHWAY – TWO PRODUCTS FOR 2020

With regard to our regulatory path, we continue the development of the Clinically Depressive Burden algorithm for FDA approval. Our aim is to identify clinical depressive burden in patients with sleep disturbance who undergo a sleep study in a sleep clinic environment. On October 29th, our Sleep Analysis of Depressive Burden (SADB) study was approved by a US-based Institutional Review Board (IRB) to start studies which will generate clinical data for a final study that will support our progress towards a De Novo submission by late 2020.

An early and essential step in this endeavour is the identification of the 5 distinct sleep stages. We have developed an algorithm that will identify these important sleep stages. Al technology for our proprietary automatic sleep staging will be used together with heart-rate variability calculation to map sympathetic and parasympathetic modulation throughout sleep cycles.

The company is pleased to advise that as a result of this work, it has identified a second potential regulatory path related to our sleep staging algorithm. As the final step, the Company is optimising the algorithm performance by undertaking a validation phase study, designed to lead to a 510(k) submission by second quarter of 2020. To date testing performance of the algorithm is showing overall accuracy in the range of human scorer agreement.

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The commercialisation path for this algorithm will target the pharmaceutical industry, academic research, and sleep centres across the US. The Company, as part of the Sleep Analysis of Depressive Burden study, has had preliminary discussions with the sleep clinic, the subject of the SADB study and their physicians, whom have found value in our work. The Company will continue to have commercial discussions as we move through the process in the form of licencing and royalty arrangement.

### MANAGEMENT CHANGES AND COMPANY RELOCATION

As part of the restructuring described above, which includes the downsizing of the Minneapolis office, Mr David Kaysen will be stepping down as CEO, Managing Director and Chairman. Mr Kaysen was appointed in November 2018 at a critical time in the Company's evolution. In a relatively short period of time Mr Kaysen reorganised the Company and laid the foundations for its future success. The Board of Medibio wishes to express its sincere gratitude for his efforts in the face of challenging circumstances. Following Mr Kaysen's resignation in the coming days, Mr Kaysen has agreed to stay on until the 31 December 2019 to ensure a smooth transition. We wish him well in his future endeavours.

We also wish to thank the senior staff of the Minneapolis office whom have worked tirelessly in assisting Mr Kaysen in realising many of the achievements in the past 12 months. Their diligence and dedication is very much appreciated by the Board.

Mr Claude Solitario will be appointed Managing Director. Mr Solitario is a founder and major shareholder of the Company and is suitably qualified to oversee the transition well into the new year. His background, experience and knowledge of the Company will prove invaluable in ensuring that the Company maintains and builds on the momentum of ilumen<sup>™</sup> and the Company's FDA program.

The terms and conditions of Mr Solitario's appointment as Managing Director will be announced to the market in due course.

Mr Peter Carlisle continues as Lead Non-executive Director. Mr Carlisle has broad insight and an extensive reach into the US market. With the early success of ilumen<sup>TM</sup>, we are now well-positioned to take advantage of Mr Carlisle's experience and knowledge of the US market.

Ms Melanie Leydin will also continue as a Non-executive Director and joint Company Secretary. Ms Leydin's experience in corporate and regulatory matters has been vital during the period of comprehensive review and we look forward to her continuing involvement.

No further board appointments are envisaged at this time.

The Company will maintain sufficient cash to meet its current responsibilities and product development.

Your Board are very excited about the opportunities ilumen<sup>™</sup> presents us, along with the continuing development of our sleep staging and depressive burden algorithms.

We look forward to your continuing support.

#### For and on behalf of the Board of Directors

Claude Solitario Director

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#### About Medibio Limited

Medibio (ASX: MEB) (OTCQB: MDBIF) is a 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 U.S. offices in 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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