ASX Announcement

Medibio Limited – 30 April 2019

Medibio Announces Regulatory and Commercialisation Strategy Update

Melbourne, Australia and Minneapolis, MN – 30 April 2019: Medibio Limited (**MEB** or the **Company**)(ASX: MEB)(OTCQB: MDBIF), a mental health technology company provides the following update on regulatory strategy.

Effective 29 April, the Company notified the FDA, and received acknowledgement from the agency, of the decision to withdraw the initial De Novo submission filed in July 2018. As previously communicated to the market, this De Novo was flawed in many ways. The decision to withdraw this submission was made after considering input from the FDA, gained through Medibio's ongoing and positive dialogue with the agency. This decision was also informed by newly engaged regulatory counsel. With this guidance, the Company has identified a revised long-term regulatory strategy allowing for more efficient use of limited staffing and cash resources and leading to more robust commercialisation opportunities.

The Company recently engaged the well-known and respected regulatory law firm of DuVal & Associates to advise on regulatory strategy. The firm, led by proven industry leader Mark DuVal, J.D., counsels companies in the medical device, pharmaceutical, biotech and other industries. The team brings a breadth of specialised experience in FDA regulations for products at all stages of the product life cycle. In particular, DuVal & Associates has extensive experience doing submission work with the FDA, has worked on many De Novo applications and participated in the first-ever De Novo panel meeting held by the FDA. The firm's stock-in-trade is its relationships with the FDA forged over many submissions, agency appeals and pre-submission meetings. DuVal & Associates represents many clients before the agency on a monthly basis.

With the specialised and expert counsel from DuVal & Associates, the Company has identified a revised regulatory strategy which includes filing a new De Novo submission in late 2019. The Company will not pursue a parallel path through 510(k) submission.

This revised strategy comes after a thorough evaluation of all FDA regulatory pathways available with these key findings:

- Further analysis on the proposed 510(k) submission revealed limited commercialisation opportunity with the 510(k) due to the limited indications for use that would be obtained.
- Upon extensive review and analysis, these limited indications ultimately did not fit with the Company's strategy. The Company is better served by building a longer-term FDA strategy for a robust and sustainable commercial pathway in the U.S., which includes a more attractive indications for use statement only obtainable through the De Novo path.

- Further, the resources required to pursue the parallel paths, De Novo and 510(k), would be prohibitive for the Company, including limiting ability to respond to increased global interest in the Corporate Health ilumen™ product now in pilot phase.

With the decision to discontinue parallel paths for De Novo and 510(k) in the U.S., the Company will have the resources needed to aggressively focus on new opportunities in both Australia and the U.S., as well as to initiate revisions to our current CE Mark and pursue commercialisation opportunities in the European Union.

"These changes in our regulatory strategy come after extensive review and analysis of all pathways currently available to us," said David B. Kaysen, Chairman, Managing Director and CEO of Medibio. "I am confident we are working with the best in the business with the advice and counsel of DuVal & Associates. These decisions on revised regulatory strategy have been extremely well thought out and made with respect to the most efficient use of our limited resources. I am confident that these decisions, while delaying any sort of FDA announcement into 2020, will provide the best long-term overall FDA strategy, and ultimately a path to revenue."

Commercialisation Strategy

With the change in regulatory strategy, the commercialisation strategy has also been refined.

U.S. Regulated Product Commercialisation Opportunities

The initial commercialisation and licensing opportunities will focus primarily on physician prescribed inpatient sleep studies.

CE Mark Commercialisation Opportunities

Upon finalisation of a revised CE Mark product, expected no later than September 2019, the Company will pursue opportunities in the European Union. Medibio will work to build strategic alliances and partnerships with Clinical Research Organizations (CRO), European Sleep Study Societies, and pharmaceutical companies.

The Company will also evaluate single-payer and private payment systems in Europe that have interest in biometric assessments of mental health as part of their reimbursement strategy.

ilumen™ Commercialisation

The Company continues to advance and consider unsolicited approaches from major global companies, the implementation of which will have regard to the Company's limited resources at this time, while continuing to seek large scale commercialisation of ilumen™. This includes new U.S. – based opportunities now in discussion.

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The Company has successfully demonstrated the stability of its ilumen™ platform through its pilot program. After finalisation of pilots now in progress in Australia, Medibio will no longer offer ilumen™ pilots. Moving forward, ilumen™ will only be offered on an annual subscription basis.

Further, Medibio will aim to integrate ilumen™ into organisations with global distribution channels. In doing so the Company will seek to generate revenue from annual license fees and royalties based on usage. Medibio will also, as and when appropriate, recoup setup costs for client customisation.

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About Medibio Limited

Medibio (ASX: MEB) (OTCQB: MDBIF) is a mental health technology company that has pioneered the use of objective biometrics to assist in the screening, diagnosing, monitoring and management of depression and other mental health conditions. The company offers comprehensive mental health solutions for business through its Corporate Health programs and is developing products to serve both the consumer and regulated healthcare provider markets. 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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