

ASX Announcement



Medibio Limited – 10 September 2018

Medibio Provides Market Update

Sydney, Australia and Minneapolis, MN USA – 10 September 2018: Medibio Limited (MEB or the Company)(ASX: MEB)(OTCQB: MDBIF), a mental health technology company, today provides a market update to the last quarterly report.

Our purpose at Medibio is clear: To improve the screening, diagnosis, monitoring, and management of mental health. We believe in our innovative technology and remain steadfast and focused on our mission to identify the link between physiological measures and mental health. Medibio is developing modern technological tools for professionals and consumers to meet this vast global health need. We are fortunate to have the experience and dedication of senior leadership and our Board of Directors to move the Company forward in the right direction as we search for a new CEO.

CEO Search Update

The Company is in the process of engaging an executive recruiting firm to select a new CEO. Peter Carlisle and Dr. Franklyn Prendergrast will help lead our Board's involvement in the CEO search.

Acting as interim CEO, Brian Mower has worked for nearly 20 years in the medical technology industry and has helped lead innovative medical technologies thru regulatory approvals and into commercialisation. We have assembled a team of technical, marketing and scientific people working on two continents, who all share a vision of making a major difference to one of the world's biggest health issues; mental health and depression.

Board of Director Update

We are pleased to announce that Peter Carlisle has been appointed as Vice-Chairman. As the Company expands in the U.S., Peter's valuable and unique skills and background in marketing, public relations and communications, contract negotiations, and law will help the company progress with our innovative mental health platform. Peter has been with the Company's board since June 2017.

Quality and Regulatory Update

As previously announced, we attained the CE Mark (May 2018) after successfully submitting our technical file, working with our notified body to achieve compliance, and establishing the required Quality Management System. In successfully accomplishing this, we enhanced our quality system and increased the efficiency within our organization. Subsequently, we attained TGA clearance from the Therapeutic Goods Association in Australia (June 2018).

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With these two achievements, we continue moving forward with the focus on FDA submission. The innovative nature of our technology required that we use the De Novo pathway for FDA submission.

After compiling research confirming the accuracy of our technology, meeting with the FDA, and progressing through the various preliminary stages, we reached a major milestone for the company in submitting our application to the FDA on Friday, July 13. Further, on 6 September 2018, we released the DX04 clinical study results in support of the FDA submission. We anticipate attaining FDA clearance in first quarter of calendar year 2019.

Scientific Publication Supporting Medibio

As previously announced, our Chief Medical Officer, Archie Defillo, was published for his paper “Physiological Differences between Mood Disorder Phenotypes Based on Heart Rate Variability” in the internationally peer-reviewed journal *EC Neurology*. This led to greater awareness of our technology and the proliferation of interest among psychiatrists, hospitals, and research institutions in Medibio’s pioneering of objective-based mental health science.

Completion of the DX04 clinical study also provides the foundation for multiple intended scientific publications supporting the advancement of our technology.

Product and Corporate Development Update

In addition to placing our clinical decision tools in the hands of general practitioners, psychologists, and psychiatrists, it is our aim to empower individuals to achieve self-awareness of mental states and take informed action to become well and stay well. Through the use of personal wearable devices, users of our technology may obtain objective insights into their own mental wellness.

Corporate Health Program

Following the acquisition of Vital Conversations in April 2018, we have continued development of our corporate health strategy to include a program that enlists employers to become actively involved in the mental health and wellness of employees. With growing employer awareness of mental health issues being one of the top causes of work-related absence and declines in productivity, we are engaging corporations to embrace a solution and enroll in our Corporate Health Program. Our first product launched in the Australian Corporate Health vertical in May 2018.

The Medibio Corporate Health app provides confidential insight to individual employees based on their biometrics and results of subjective check-ins. Additionally, the corporate customer gains access to an anonymized, company-wide, or department-specific dashboard view of the mental health of their workforce. Our team is actively securing annualized subscription contracts for products and services with multiple entry points tailored to organisational need. Pricing, which will vary by program design, is expected to range between \$15-\$45 per employee.

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We have signed clients, including Jacobs Engineering, Australian Football League (AFL), St. John of God Healthcare, Rio Tinto, among others, to initial program contracts. As of June 30, 2018, the Company had realized approximately \$150,000 of revenue associated with the new acquisition since April 2018.

The Company has further invested significant resources on preparing for the October 2018 launch of the second release of its Corporate Health product to coincide with Australia's Mental Health Month and World Mental Health Day.

Consumer Health

Our research and development of new applications for the Consumer Health program continues. We anticipate opportunities for this technology in 2019, through wearable device integration and consumer-focused mobile applications.

Integrated Health

As we await FDA clearance for the Medibio diagnostic aide product, we continue to aggressively add to the intellectual property portfolio to support multiple use cases that leverage the platform. We are developing our Integrated Health program which has the potential to improve outcomes for mental health care by enabling doctors to observe mental states of patients. For the first time, physicians would have the ability to monitor the real-time effects of psychiatric treatment on patients during outpatient care, where most treatment of mental illness occurs. In addition, this would allow patients to track their biometric data and engage in dialogue with their physicians through the platform, while they are away from the treatment center or physician office.

We are excited to welcome Lindsey Hagan as VP of Integrated Health Systems. She will partner with the technology and clinical teams on product strategy and lead business development initiatives to grow integrated health system provider relationships. Lindsey has more than 13 years of sales experience working with medical device, technology, pharmaceutical, and healthcare organizations. Most recently, she was Regional Sales Manager at StemoniX where she played an integral role in the launch of microBrain 3D and built partnerships with pharmaceutical companies.

Otsuka Agreement

The agreement between Otsuka and Medibio progressed through several phases, as Medibio provided its advanced proprietary analytic technology to select Otsuka data. During the completed phases, the parties realized the need for additional data to meet overall objectives and the parties extended the agreement to better assess specific needs. The term of the extension has expired, and the parties are in discussion to further extend the agreement. The Company is interested in continuing its work with Otsuka on completing the assessment and on other potential projects.

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Closing

We continue what was a transformational year at Medibio. With the expansion of our patent portfolio, development of world-class technology, a successful acquisition, and many regulatory achievements, our team has begun the journey into commercialisation. We remain committed to exceptional product quality and operational excellence and continue to work towards transforming mental health care delivery, objectively.

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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 digital biomarkers to assist in the screening, diagnosing, monitoring and management of depression and other mental health conditions. The company was founded in Australia, with offices located in Melbourne (Vic), Perth (Wa) 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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