

ASX Announcement

Medibio Limited – 30th April 2020



Quarterly Activities Report and Appendix 4C

Key highlights from the quarter:

- Medibio submitted a 510K application to the FDA for its sleep staging medical software, MEBsleep (previously known by its working title: STAGER).
- MEBsleep is currently showing an overall accuracy of 84.7%, which is superior to its chosen predicate device.
- MEBsleep's overall accuracy compares favourably to certified sleep technicians, currently considered the gold standard but has considerably faster processing time (2 minutes vs 60-90 minutes per file).
- Signed Annual Services agreement with global engineering, design and related professional services firm Stantec Australia for ilumen™.
- Signed a Memorandum of Understanding (MOU) with global independent end-to-end IT services company DXC for ilumen™.
- Completed a fourth and final ilumen™ pilot completed with global food services company Compass Group PLC.
- Advanced discussions with Compass Australia and DXC regarding promotion of ilumen™ to their respective substantial client base.
- Appointed Ms Kelly Trupkovic as Partnerships and Marketing Manager in Melbourne, Australia to accelerate the growth of ilumen™.
- Engaged Dr Stephen Addis as a medical consultant to support the growth of ilumen™

Melbourne, Australia and Minneapolis, MN – 30 April 2020: Medibio Limited (MEB or the Company) (ASX: MEB) (OTCPINK: MDBIF), a mental health technology company is pleased to provide the following March quarterly update.

Commenting on activities completed during the quarter, Managing Director Claude Solitario said:

"I am extremely pleased to report on a quarter of solid progress at Medibio. This is particularly pleasing given the disruption caused by the recent restructuring and of course, the extraordinary circumstances surrounding COVID-19. Despite these challenges, our team in Minneapolis has today submitted to the FDA a 510K application for our sleep staging medical software, MEBsleep. This submission is on time and on budget. We are now actively seeking commercial opportunities for MEBsleep in anticipation of FDA clearance by August this year.

I am also very pleased to report we have made significant progress during the quarter with the commercialisation of ilumen™. Given our limited financial resources, management has focused predominantly on global entities with the capacity to distribute ilumen™ widely. We believe that although engaging global companies requires time and patience, the benefits and return on capital will be beneficial in the longer term. We are now in meaningful discussions with both Compass Australia and DXC regarding promoting ilumen™ to their respective substantial client base, many of which are being driven in part by

ASX Announcement



Medibio Limited – 30th April 2020

the COVID-19 crisis. I thank you for your attention to our March quarterly report and for your continuing support.”

Clinical Update

On Wednesday 29th April, Minneapolis time, Medibio submitted to the FDA a 510K application for its sleep staging medical software, MEBsleep. The application is on time and on budget. This is despite the disruption caused by the Company’s reorganisation early this quarter; and the significant COVID-19 restrictions in Minneapolis late in the quarter.

MEBsleep is medical software that analyses physiological signals (EEG and ECG) obtained during sleep via polysomnography (PSG). MEBsleep reads the EEG signals and assigns sleep stages (i.e. Wake, N1, N2, N3, REM) to each 30-second epoch of data in accordance with the American Academy of Sleep Medicine guidelines. It was developed and tested using more than 1 million epochs (an epoch is a 30-second sleep interval) in over 1,000 individuals.

The trial for the purpose of the 510k application was designed to evaluate the effectiveness of the MEBsleep software in analysing EDF files from PSG in adult subjects. The trial data was captured for analysis from a retrospective, cross-sectional, multi-centre study. The overall percent agreement was 84.70% (95% percentile bootstrap CI: 82.95% - 86.27%), which resulted in significantly greater accuracy than the overall percentage agreement of the chosen predicate device (73%). Moreover, all positive and negative percent agreement measures also resulted in significantly greater accuracy than the predicate device. The final result of the trial is summarised below:

	MEBsleep Upper Bound of 95% Confidence Interval	Predicate Point Estimates	Pass/Fail
Positive Percent Agreement			
WAKE	85%	73%	Pass
N1	56%	25%	Pass
N2	90%	77%	Pass
N3	95%	76%	Pass
REM	94%	74%	Pass
Negative Percent Agreement			
WAKE	99%	94%	Pass
N1	96%	93%	Pass
N2	92%	84%	Pass
N3	99%	94%	Pass
REM	99%	97%	Pass

ASX Announcement



Medibio Limited – 30th April 2020

The speed (1-2 minute analysis by MEBsleep vs 60-90 minutes with a technician), accuracy and the AI characteristics of MEBsleep offers significant advantages over other sleep staging software in the market. Medibio is now seeking commercial opportunities in the USA in anticipation of FDA clearance.

Furthermore, the Company will be submitting MEBsleep for CE Mark approval, which will allow commercialisation in Europe.

Regrettably, the closures of sleep clinics across America as a result of COVID-19 has hindered the progress of the Company's depressive burden trial. However, the Company stands ready to resume the trial as and when the various sleep clinics reopen in the USA. The Company has contingency plans including increasing the number of trial sleep centre sites beyond the Lakeland Health Services, University of Florida, Mayo Clinic and Mount Sinai, in order to make up for lost time.

For additional information relating to the De Novo Application for Depressive Burden (MEB-001), the 510K submission for Sleep Staging and Heart Rate Variability Algorithms (MEBsleep) in 2020 and Potential CE Mark submission for MEBsleep in 2020, see Medibio's announcement dated 14 February 2020, or [click here](#).

ilumen™ Commercial Update

In February, the final paid commercial trial was completed with global food services company Compass Group PLC. ilumen™ has now been piloted across four Compass divisions globally namely, Financial Services, Offshore & Remote (UK and Australia) and Defence. These pilot programs generated insights into employee and organisational wellbeing and were well received by Compass management. Discussions are now well advanced with Compass in relation to the promotion of ilumen™ to its substantial client base with a focus on the Remote & Offshore division in Australia.

During the quarter, Medibio also entered a Memorandum of Understanding (MOU) with the world's leading independent end-to-end IT services company DXC Technology (NYSE: DXC). DXC provides Australian and global businesses with best-in-class cloud, mobility, security, application development and modernisation, IT, workplace, big data analytics and business process services across a range of industries. The company's global scale and innovation platforms serve more than 6,000 private and public-sector customers in 70 countries.

The purpose of the MOU is to establish the framework for collaboration between Medibio and DXC to foster a strong working relationship that provides increased opportunities for the commercial success of ilumen™ in Australia, the US and worldwide. Discussions are well advanced and focussed on promoting ilumen™ to DXC's substantial Australia-wide client base, focussing on their mining and resources clientele, amongst others. In particular, ilumen™ will form a part of the suite of services that DXC will offer their client base in order to meet the challenges of COVID-19. Medibio is proud to be a part of this strategy.

ASX Announcement



Medibio Limited – 30th April 2020

During the quarter the company signed an annual licence agreement with global engineering, design and related professional services firm Stantec Australia, to provide ilumen™ to 1,500 Stantec employees in Australia and New Zealand.

During the quarter Medibio also welcomed Ms Kelly Trupkovic as Partnerships and Marketing Manager for the APAC Region and Dr Stephen Addis as a medical consultant to its executive team to support and accelerate the growth of ilumen™.

The appointment of a dedicated sales and marketing professional such as Ms Trupkovic has allowed Medibio to accelerate the development of a sales and prospects pipeline. Ms. Trupkovic has over 15 years' experience gained from a range of Australian and multinational organisations within the financial services sector, specifically Group Risk and Corporate Superannuation arenas where she focused her time and efforts in key account management, sales and business development.

Dr Addis is a founding shareholder and an early contributor to the intellectual property upon which the Company was built. He is a former Head of Psychiatry at Fremantle Hospital, a large university teaching hospital in Western Australia. He has over a decade of clinical research into the effects of mental illness upon the circadian heart rate; research that forms the basis of the Company's intellectual property.

Medibio is now seeing heightened interest in and demand for ilumen™ due to COVID-19. The Company is responding to this increased demand by working closely with its current corporate clients and optimising prospective opportunities to maximise access to, implementation of, and support for ilumen™.

We look forward to a productive period for ilumen™ as we enter the final quarter of the 2020 financial year.

Corporate and Financial Update

The Company's cash position at 31st March 2020 was approximately \$1,025,000. The Company had cash receipts from customers of approximately \$24,000, received its 2019 R&D tax incentive grant amounting to approximately \$674,000 and had research and development expenditure of approximately \$386,000 during the quarter.

Payments to related parties and their associates during the quarter was \$0.29m. These payments related to Director fees, consulting fees and Director entitlements in relation to the former Managing Director, CEO and Chairman of approximately \$0.16m following his resignation as outlined in section 6 of the Appendix 4C. Ms Melanie Leydin, Director and Joint Company Secretary, was compensated for company secretarial services via payments to Leydin Freyer Corp Pty Ltd included within the payments. Non-Executive Directors are no longer remunerated by means of cash for services.

ASX Announcement



Medibio Limited – 30th April 2020

The Company continues to review its funding options and is currently in discussions in relation to a number of options. The Company also continues to constantly review its levels of expenditure to ensure that it manages its resources as efficiently as possible and in the best interests of shareholders.

– ENDS –

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

About Medibio Limited

Medibio (ASX: MEB) (OTCPINK: 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 OTC Pink Open Market. Investors can find additional information on www.otcmarkets.com and www.asx.com.au.

Further Information:
Medibio Investor and Media Enquiries: Peter Taylor NWR Communications peter@nwrcommunications.com.au T: +61 (0) 412 036 231

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

MEDIBIO LIMITED

ABN

58 008 130 336

Quarter ended ("current quarter")

31 March 2020

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	24	109
1.2 Payments for		
(a) research and development	(386)	(1,213)
(b) product manufacturing and operating costs	-	(1)
(c) advertising and marketing	(3)	(8)
(d) leased assets	-	-
(e) staff costs	(539)	(1,593)
(f) administration and corporate costs	(967)	(2,075)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	7
1.5 Interest and other costs of finance paid	(18)	(18)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	674	674
1.8 Other (IP expenditure)	-	-
1.9 Net cash from / (used in) operating activities	(1,215)	(4,118)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	(399)
(f) other non-current assets	-	-

Quarterly cash flow report for entities subject to Listing Rule 4.7B

2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	-	(399)
3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	4,711
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(479)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	-	4,232
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	2,204	1,333
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,215)	(4,118)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(399)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	4,232
4.5	Effect of movement in exchange rates on cash held	36	(23)
4.6	Cash and cash equivalents at end of period	1,025	1,025

5. Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1 Bank balances	1,025	2,204
5.2 Call deposits	-	-
5.3 Bank overdrafts	-	-
5.4 Other (provide details)	-	-
5.5 Cash and cash equivalents at end of quarter (should equal item 4.6 above)	1,025	2,204

6. Payments to related parties of the entity and their associates

6.1 Aggregate amount of payments to related parties and their associates included in item 1	289
6.2 Aggregate amount of payments to related parties and their associates included in item 2	-

**Current quarter
\$A'000**

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

7. Financing facilities

Note: the term "facility" includes all forms of financing arrangements available to the entity.

Add notes as necessary for an understanding of the sources of finance available to the entity.

	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 Total financing facilities	-	-

7.5 Unused financing facilities available at quarter end

-

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

N/A

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (Item 1.9)	(1,215)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	1,025
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	1,025
8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	0.84

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

1. Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:

The cash outflow for the June 2020 quarter will be less than that of the previous quarter due to substantial restructuring of the company's business that included relocating much of the company's USA operations to Australia; and in doing so providing a greater focus on some of the activities in both countries.

2. Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer:

The Company is considering raising further capital and the Board believes the Company will be successful in raising the capital it needs due to the recent restructuring, which has resulted in substantially lower operating costs, increased efficiencies and heightened future prospects and the opportunities that will create shareholder value (see 3 below)

3. Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:

The Company does expect to be able to continue its operations and to meet its business objectives. The Company has submitted a 510K application to the FDA for its sleep staging medical software device, known as MEBsleep (previously known by its working title, STAGER). MEBsleep is a necessary step in the Company's pursuit of its depressive burden medical software device. However, MEBsleep has commercial value in itself. Subject to 510K clearance by the FDA (expected within 3 months of submission), MEBsleep will be ready for early commercialisation. The Company is also considering a CE Mark application for MEBsleep, which will enable commercialisation in Europe.

In addition, the Company is pursuing opportunities for its corporate mental health wellness product, ilumen™, on the basis of the heightened demand due to the COVID-19 pandemic. The Company is currently responding to this demand by working closely with its current corporate clients and optimising prospective opportunities to maximise access to, implementation of, and support for ilumen™. These discussions involve a number of corporations both in Australia and internationally.

Please refer to the March Quarterly Activities Report for further details of the operations of the Company.

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 30 April 2020

Authorised by: By the Board.....
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.