# **ASX Announcement**

Medibio Limited – 30 July 2020



# June Quarterly Activities Report and Appendix 4C

Key highlights from the quarter:

- Submitted FDA 510K application for sleep staging medical software, MEBsleep
- Discussions well advanced on the commercialisation of ilumen™
- Resolved the final "legacy" dispute begun under a previous management regime
- Successfully completed a Placement for \$0.5M
- Successfully completed a fully underwritten Entitlement Offer for \$1.5M (post quarter end).

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

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

"Medibio's operations continue to progress with solid gains across the regulated and non-regulated business units. Early in the June quarter we were pleased to lodge a 510K application for our sleep staging medical software, MEBsleep as assured, on time and on budget. Discussions are progressing on a number of fronts including Compass and DXC regarding the commercialisation of ilumen™. We also resolved the final "legacy" dispute begun under a previous management regime. We finished the quarter having successfully completed a Placement for \$0.5M and securing a fully underwritten Entitlement Offer for \$1.5M completed in July.

These achievements were particularly pleasing given they were made during the interruption of the recent restructure and reorganisation of the Company, followed shortly thereafter by the significant disruption caused by COVID-19.

Looking forward, sleep clinics in some parts of the USA have reopened following the COVID-19 lockdown. This has enabled us to i) re-commence the Depressive Burden trial; and ii) explore avenues for commercialisation of MEBsleep, in anticipation of FDA clearance. The funding secured during the June quarter will greatly assist in this endeavour, as well as continuing commercialisation efforts for ilumen and commencing the development of the Consumer App.

We look forward to another productive quarter ahead. I thank you for your interest in Medibio Ltd".

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ACN: 008 130 336

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### **Clinical Update**

On Wednesday 29<sup>th</sup> April, Medibio submitted a 510K application to the FDA for its sleep staging medical software, MEBsleep. This was particularly pleasing given the disruption caused by the Company's reorganisation in the months leading to the submission; and the lockdown in Minneapolis late in the quarter due to COVID-19. The Company advises that it is currently in constructive dialogue with the FDA. The Company will provide an update on progress shortly.

MEBsleep is medical software that analyses physiological signals (EEG and ECG) obtained during sleep via polysomnography (PSG). The trial for the purpose of the 510k application was designed to evaluate the effectiveness of the MEBsleep software in the various sleep stages in adult subjects. The trial data was captured for analysis from a retrospective, cross-sectional, multicenter study. The overall percent agreement was 84.70%, which resulted in significantly greater accuracy than the overall percentage agreement of the chosen predicate device (73%). Further details of the result of the study may be seen here.

Importantly, the speed (1-2 minute analysis by MEBsleep vs 60-90 minutes by a technician), accuracy and the AI characteristics of MEBsleep offers significant advantages over other sleep staging software in the market. Medibio is now planning for commercial opportunities in the USA in anticipation of FDA clearance, expected in August 2020. Furthermore, the Company will shortly be submitting MEBsleep for CE Mark approval, which will allow commercialisation in Europe.

Following the reopening of some sleep clinics across America late in the June quarter, after COVID-19 closures, the Company has re-commenced its Depressive Burden trial.

### ilumen™ Commercial Update

In May this year global engineering, design and related professional services firm Stantec Australia commenced providing ilumen™ to its 1,500 employees in Australia and New Zealand. To date, Stantec has had a very positive employee participation in the program. Discussions are also underway regarding rolling out ilumen™ to geographies other than Australia and New Zealand.

Discussions regarding the re-sale and implementation of ilumen<sup>™</sup> both in Australia and internationally are well advanced with Compass Group PLC in London; and separately with its Australian subsidiary, following the successful completion of a number of paid pilot programs. As the vision is to implement ilumen<sup>™</sup> in various parts of the world, the data privacy and security requirements demanded of ilumen<sup>™</sup> are of the highest order. Medibio management in Australia and the USA are working diligently to ensure these high standards that are being demanded are met.

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Discussions are also on-going with DXC regarding a Re-seller Agreement, whereby DXC will promote ilumen<sup>™</sup> to its substantial client base. During the June quarter Medibio staff provided ilumen<sup>™</sup> product training to their extensive team of sales professionals. ilumen<sup>™</sup> is the mental wellness solution in a suite of products that DXC is offering as part of the COVID-19 solution response.

Medibio are also in varying degrees of discussions with a number of global organisations, including insurers, benefits management and Employee Assistance Providers (EAP's), who are seen to be key strategic partners.

### **Corporate and Financial Update**

The Company's cash position at 30th June 2020 was approximately \$810,000. During the June quarter the Company raised \$0.5M by way of a placement of 83,333,333 shares at an issue price of \$0.006 per share (before costs) from sophisticated, professional and other exempt investors. The Company also secured approximately \$1.5M via a fully underwritten Non-Renounceable Entitlement Offer at an issue price of \$0.006 per share (before costs). The full details of the capital raising may be seen <a href="here">here</a>.

Payments to related parties and their associates during the quarter was \$0.075m. These payments related to Director fees and remuneration of their associates. 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.

- 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:**

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# **Appendix 4C**

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

## Name of entity

MEDIBIO LIMITED		
ABN Quarter ended ("current quarter")		
58 008 130 336	30 June 2020	

Cor	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	34	143
1.2	Payments for		
	(a) research and development	(310)	(1,523)
	(b) product manufacturing and operating costs	(1)	(2)
	(c) advertising and marketing	-	(8)
	(d) leased assets	-	-
	(e) staff costs	(311)	(1,903)
	(f) administration and corporate costs	(135)	(2,381)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	8
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	74	748
1.8	Other (IP expenditure)	17	169
1.9	Net cash from / (used in) operating activities	(632)	(4,749)

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	-	-

ASX Listing Rules Appendix 4C (01/12/19)

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)	500	5,211
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	500	4,732

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	1,026	1,333
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(632)	(4,749)
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)	500	4,732
4.5	Effect of movement in exchange rates on cash held	(84)	(107)
4.6	Cash and cash equivalents at end of period	810	810

ASX Listing Rules Appendix 4C (01/12/19) + See chapter 19 of the ASX Listing Rules for defined terms.

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	810	1,026
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)	810	1,026

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	75
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

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.

- 7.1 Loan facilities
- 7.2 Credit standby arrangements
- 7.3 Other (please specify)
- 7.4 Total financing facilities

Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
-	-
-	-
-	-
-	-

### 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)	(632)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	810
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	810
8.5	Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	1.28

ASX Listing Rules Appendix 4C (01/12/19)

- 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 Company undertook significant cost cutting measures during the June quarter. A reduction of activities due to COVID-19 also aided in reducing costs. The Company does not foresee a significant increase in current level of net operating cash flows for the time being.

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:

In June 2020, the Company completed a Share Placement for \$500,000, funds of which were received during the June quarter. Also in June, the Company entered into a fully underwritten Entitlement Offer to raise a further \$1.52 million in which it announced the results subsequent to year end.

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 on the basis of the capital raised as per 8.6.2 above.

### **Compliance statement**

- 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 July 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.