

ASX Announcement  
Medibio Limited – 29 October 2020

## September 2020 Quarterly Activities Report and Appendix 4C

Key highlights from the quarter:

- **Recommenced depressive burden trial following re-opening of sleep clinics in the US.**
- **Signed clinical trial agreement with the leading sleep laboratory service provider in the US.**
- **Submitted request for Breakthrough Device Designation to FDA for depressive burden trial.**
- **Confirmed US patent granted for monitoring stress conditions using heart rate.**
- **Commenced planning and development of Consumer App.**

**Melbourne, Australia and Minneapolis, MN – 29 October 2020:** Medibio Limited (MEB or the Company) (ASX: MEB) (OTCPINK: MDBIF), a mental health technology company is pleased to provide the following update for the September 2020 quarter.

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

*“The September quarter was another quarter of significant progress in both the regulated and non-regulated business units, as detailed below. Regrettably there have been delays in achieving the milestones in the timeframe as outlined in our investor presentation dated June 2020 (see them [here](#)). These delays have been out of the Company’s control, nevertheless we remain confident that the milestones will be achieved.*

*I thank you for your continuing support and look forward to updating the market on progress during the December quarter.”*

### **Regulated Business Unit Update**

The depressive burden trial recommenced during the September quarter with Lakelands Sleep Clinic in Minneapolis. In addition, on 24 August, Medibio signed a Clinical Trial Agreement (“CTA”) with MedBridge Healthcare LLC (“MedBridge”). MedBridge is the leading provider of sleep laboratory management services in the United States, operating over 130 sleep disorder diagnostic centres. Under the CTA, MedBridge, in collaboration with Ohio Sleep Solutions in Columbus, Ohio, will coordinate research guidelines and services for the purposes of the depressive burden trial. This collaboration is significant as MedBridge provides Medibio access to many sleep clinics that will enable the Company to fast-track patient recruitment, in addition to valuable market intelligence for Medibio’s regulated products during development.

As part of the strategy regarding the depressive burden trial, on 30 September Medibio submitted a “Breakthrough Device” request with the FDA. The Breakthrough Devices Program is for devices that promise a more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or

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conditions, and meet at least one of the following criteria: (a) represents breakthrough technology; (b) no approved or cleared alternatives exist; (c) offers significant advantages over existing approved or cleared alternatives; or (d) device availability is in the best interest of patients.

The benefits of receiving Breakthrough Device Designation would include the ability to fast-track the review and assessment of the depressive burden trial and additional opportunities to interact with FDA senior management prior to its submission for approval. The FDA communicates its decision to grant or deny Breakthrough Device Designation within 60 calendar days of receiving the request.

In relation to Medibio's 510(k) application for MEBsleep, as previously reported, on 24 August Medibio received communication from the FDA that its application was found to contain all the necessary elements needed to proceed with a substantive review. Medibio continues to be in communication with the FDA and remains optimistic of clearance, as we are for CE Mark in relation to European clearance.

### **Non-regulated Business Unit Update**

#### *Patent Protection*

During the September quarter, Medibio was granted a US patent relating to a software method, using machine learning, for monitoring stress conditions by analyzing heart rate collected during sleep, including a pre-sleep period and a post-sleep period. The patent will play an important part in protecting Medibio's corporate product offering, ilumen; and its consumer app currently under development.

#### *Corporate Health - ilumen™*

User feedback of ilumen™, through its foundational licensees PwC and Stantec, has been very positive, and during the September quarter, Stantec expanded its use of ilumen™ to include its team in India; and PwC has confirmed it will renew its license for a second year.

Also during the quarter, a Master Services Agreement was signed with a global property group that owns, develops and manages industrial real estate in 17 countries. The initial implementation of ilumen™ is focused on the group's offices in Hong Kong and Greater China.

Medibio entered the legal documentation phase with a global food and other service company based in London for a license to utilize ilumen™ across its industry segments and geographic locations, and also those of their client companies, according to market demand. Negotiations are progressing well, albeit slower than anticipated due in part to COVID-19 restrictions and additional data privacy and security requirements, which have now been satisfied. Medibio will update the market on this separately in due course.

#### *Consumer Health – Consumer App*

Another noteworthy development in July was the planning of the Consumer App, which is now well advanced. The Consumer App will be available on Android or IOS to any individual that has an interest in

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assessing and monitoring their levels of stress. The App functionalities and design features have been settled upon. The biometric functionality, which will be the unique selling proposition, is currently being developed by Medibio's regulatory team.

Medibio's Consumer App will be the only app that will offer an objective assessment of stress based on the user's biological markers such as heart rate, sleep quality and activity levels. This will be supplemented by a psychometric test that the user may also undertake in combination with the biometric test, or in isolation if the user does not have a wearable device. A prototype with the full feature set for presentation purposes is scheduled for the end of 2020.

### **Corporate and Financial Update**

In July 2020 the Company raised approximately \$1.5M pursuant to a fully underwritten Non-Renounceable Entitlement Offer at an issue price of \$0.006 per share (before costs). The Company's cash position at 30 September was approximately \$1,084,000. Cash flow for the September quarter was in accordance with budgetary expectations. An additional receipt of approximately \$720,000 as a result of the Company's R&D tax rebate claim, is anticipated in the December quarter.

Payments to related parties and their associates during the quarter was \$0.12m. 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 authorized for release to the market by the Board of Directors of Medibio Ltd.

### **About Medibio Limited**

Medibio (ASX: MEB) (OTCQB: MDBIF) is a mental 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 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](http://www.otcmarkets.com) and [www.asx.com.au](http://www.asx.com.au).

### **Further Information:**

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ACN: 008 130 336

## 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")**

30 September 2020

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(21)	(21)
(b) product manufacturing and operating costs	(39)	(39)
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(159)	(159)
(f) administration and corporate costs	(379)	(379)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	85	85
1.8 Other (IP expenditure)	13	13
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(500)</b>	<b>(500)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	(473)	(473)
(f) other non-current assets	-	-

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## 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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(473)</b>	<b>(473)</b>
<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	1,517	1,517
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	(210)	(210)
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)	(41)	(41)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>1,266</b>	<b>1,266</b>
<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	813	813
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(500)	(500)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(473)	(473)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,266	1,266
4.5	Effect of movement in exchange rates on cash held	(22)	(22)
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>1,084</b>	<b>1,084</b>

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

<b>5. Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1 Bank balances	1,084	813
5.2 Call deposits	-	-
5.3 Bank overdrafts	-	-
5.4 Other (provide details)	-	-
<b>5.5 Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>1,084</b>	<b>813</b>

<b>6. Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1 Aggregate amount of payments to related parties and their associates included in item 1	120
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.*

<b>7. Financing facilities</b> <i>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.</i>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
<b>7.4 Total financing facilities</b>	<b>-</b>	<b>-</b>
<b>7.5 Unused financing facilities available at quarter end</b>		<b>-</b>
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)	(500)
8.2	Cash and cash equivalents at quarter end (item 4.6)	1,084
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	1,084
8.5	<b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>2.2</b>
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>		
8.6	If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1	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: N/A	
8.6.2	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: N/A	
8.6.3	Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
	Answer: N/A	
<i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>		

### 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: 29 October 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.