

ASX Announcement
Medibio Limited – 29th January, 2021

December 2020 Quarterly Activities Report and Appendix 4C

Key highlights from the quarter:

- **Signed Global Master License and Services Agreement with Compass Group Plc. for ilumen**
- **Signed a Clinical Trial Agreement with US-based MedBridge Healthcare LLC for the Depressive Burden trial.**
- **Received feedback from US Food and Drug Administration (FDA) and guidance that additional data may be required for 510(k) approval of sleep staging software device, MEBsleep.**
- **Progressed Development of Consumer App according to plan.**

Melbourne, Australia and Minneapolis, MN – 29 January 2021: Medibio Limited (MEB or the Company) (ASX: MEB) (OTCPINK: MDBIF), is pleased to provide the following update for the December 2020 quarter.

Regulated Business Unit Update

Sleep Analysis of Depressive Burden (“SADB”) trial (MEB-001) and Medbridge Healthcare LLC

In October 2020, Medibio entered into a Clinical Trial Agreement (“CTA”) with MedBridge Healthcare LLC (“MedBridge”) to support Medibio’s SADB trial which aims to identify clinical depressive burden in sleep-disturbed patients undergoing a sleep study in a clinical environment. MedBridge recognizes the importance of identifying depression among patients suffering from sleep disturbance and the potential of Medibio’s technology and its clinical application to address this unmet need.

MedBridge is the leading provider of sleep laboratory management services in the United States, operating over 130 sleep disorder diagnostic centres and performing over 70,000 sleep disorder diagnostic procedures annually. MedBridge partners with hospitals and physician practices to offer comprehensive, fully-integrated services for the identification, testing, diagnosis, therapeutic coordination, and long-term care management of patients with sleep disorders.

Under the CTA, MedBridge, in collaboration with Ohio Sleep Solutions in Columbus, Ohio, will coordinate research guidelines and services for the SADB trial to help fast-track patient recruitment.

Breakthrough Device Designation

In September 2020, Medibio submitted an application with the FDA for “Breakthrough Device Designation” for its Depressive Burden software platform, MEB-001, in an effort to fast-track the application process in response to the heightened mental health concerns resulting from the COVID-19 pandemic and resulting economic conditions.

Inaccurate and inadequate diagnosis is a major barrier to effective treatment of depression, contributing to its recurrence and increasing the likelihood it will lead to a life-threatening disorder. By providing an objective measure of depressive burden, MEB-001 reduces the bias associated with self-report

questionnaires and facilitates help-seeking behavior; in addition the resulting increase in accuracy and efficiency allows for a reduction in costs currently borne by the healthcare system.

In November 2020, the FDA notified Medibio that its application for Breakthrough Designation did not satisfy the FDA's Breakthrough Device criteria. The Company is currently in discussions with the FDA regarding its decision and providing further clarification of Medibio's technology.

MEBSleep 510(k) Application

In April 2020, Medibio submitted an 510(k) application for its sleep staging software, MEBSleep. In December 2020, the FDA advised it requires a larger sample of clinical data better reflecting the proposed intended use population, in order for it to be considered substantially equivalent to its chosen predicate device. The FDA also provided a detailed pathway as to how Medibio may achieve approval for MEBSleep and invited the company to discuss the additional steps required.

Following subsequent extensive consultations, the FDA have since indicated that new data may not be required. Therefore should Medibio elect to submit a new 510(k) application, it may be prepared quickly and cost-effectively.

Whilst regulatory approval is not required for MEBSleep's primary purpose as an integral part of the depressive burden software device MEB-001, the Company believes MEBSleep is of commercial value and represents an early revenue opportunity in the clinical sector.

It is also important to note that this program has not affected the progress of the depressive burden trial which is Medibio's primary objective.

Non-regulated Business Unit Update

Corporate Health – ilumen

In November 2020, Medibio signed a three-year Global Master License and Services Agreement (GLA) with Compass Group Plc. for Medibio's corporate mental health product, ilumen. Compass is a multinational corporation providing contract food and related support services across a number of industry groups, including Business & Industry, Defence, Offshore & Remote, Education, Healthcare and Sports & Leisure.

Under the terms of the Agreement, Medibio will make ilumen available to Compass Group companies electing to implement the technology for the benefit of their employees. The agreement also grants Compass Group companies the right to license ilumen to their client companies, which include many multinational corporations.

Revenue generation, which Medibio expects to be material, will depend on the rate and level of adoption by Compass Group companies and their client companies. The annual licence fee is a SaaS (Software as a Service) fee calculated per-employee, per annum based on the size of the workforce of the particular company enrolled in the program, regardless of the level of employee participation.

Since executing the GLA, Medibio has been working with Compass Head Office in London to identify opportunities to implement ilumen amongst Compass companies and Compass client companies. Discussions are also ongoing with a number of Compass companies around the world, including Compass Australia regarding implementation for its internal staff and significant clients in the Australian mining and

resources sector.

Medibio is also in discussions with the North American head office of an existing ilumen client to implement ilumen broadly across its organisation in the U.S. This helps to vindicate the value that ilumen brings to an organization and importantly may represent Medibio's first step into the U.S. market.

All of these discussions are progressing well albeit slower than they would otherwise without travel constraints due to border restrictions.

Consumer Health – Consumer App

The COVID-19 pandemic and its many social and economic consequences has exacerbated mental health conditions amongst the global population. In the United States, the increased stress and worry has adversely impacted the mental health of an estimated fifty-three percent of adults¹. Medibio intends to address this increased need and demand for mobile mental wellness through its Consumer App, which will be made available on Android and iOS platforms.

The Company's pioneering work in the use of biometric data to aid in the early detection and screening of mental health conditions, together with its patented method of assessing stress by monitoring overnight heart rate², underpins the functionality of Medibio's Consumer App, which includes both biometric and psychometric assessments.

The Consumer App's unique biometric functionality matches day and night heart rate activity and its variability throughout the night (drawn from wearable devices such as Garmin or the Apple Watch) against sleep architecture parameters and physical activity levels, producing an overall daily score to help users objectively measure, monitor, and manage stress levels and improve them over time. This unique feature will set it apart from competitors in the marketplace. Our market research indicates no other viable in-store mental health app has patent protected biometric functionality.

Development work of the consumer app progressed according to plan during the December quarter. The commercial launch in the USA is expected in advance of Mental Health Awareness Week in October 2021.

Corporate and Financial Update

The Company's cash position at 31 December 2020 was approximately A\$832,000. During the quarter the Company received the R&D incentive payment of \$803k and expended \$315k on R&D activities. The Company's development of its intellectual Property continued with expenditure during the quarter of \$301k on costs associated with MEB001 and MEBSleep FDA and 510k approval and submission process and other general IP costs.

Payments to related parties and their associates during the quarter was approximately A\$0.11m. These payments related to Director fees and remuneration of their associates. Ms Melanie Leydin, Director and

¹ <https://www.kff.org/coronavirus-covid-19/issue-brief/the-implications-of-covid-19-for-mental-health-and-substance-use/>

² U.S. Patent "Method and System for Monitoring Stress Conditions" granted 5th May 2020.

Joint Company Secretary, was compensated for company secretarial and accounting services via payments to Leydin Freyer Corp Pty Ltd, which is 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 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

58 008 130 336

Quarter ended ("current quarter")

31 December 2020

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	41	41
1.2 Payments for		
(a) research and development	(315)	(336)
(b) product manufacturing and operating costs	(34)	(73)
(c) advertising and marketing	(26)	(26)
(d) leased assets	-	-
(e) staff costs	(170)	(329)
(f) administration and corporate costs	(264)	(643)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	1	1
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	863	948
1.8 Other (IP expenditure)	14	27
1.9 Net cash from / (used in) operating activities	110	(390)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	(301)	(774)
(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	(301)	(774)
3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	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)
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)	(27)	(68)
3.10	Net cash from / (used in) financing activities	(27)	1,239
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	1,084	813
4.2	Net cash from / (used in) operating activities (item 1.9 above)	110	(390)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(301)	(774)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(27)	1,239
4.5	Effect of movement in exchange rates on cash held	(34)	(56)
4.6	Cash and cash equivalents at end of period	832	832

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

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	832	1,084
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)	832	1,084

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	110
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 <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>	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)	110
8.2 Cash and cash equivalents at quarter end (item 4.6)	832
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	832
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	N/A
<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 January 2021

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.