

# ASX Announcement



Medibio Limited – 30 April 2021

## March 2021 Quarterly Activities Report and Appendix 4C

Key highlights from the quarter:

- Sleep analysis of depressive burden (“SADB”) trial moving forward and depressive burden algorithm development progressing well.
- Two abstracts accepted at “SLEEP 2021” the 35<sup>th</sup> annual meeting of the U.S. Associated Professional Sleep Societies and the American Academy of Sleep Medicine.
- CE Mark approval granted for MEBsleep.
- Independent review of MEBsleep recommends FDA 510(k) resubmission.
- Ilumen roll-out begins in the UK pursuant to the Global Master Service Agreement with Compass Group Plc.
- Consumer App begins test phases and on track for October 2021 launch.
- Concluded successful capital raise of A\$4m.

---

Melbourne, Australia and Minneapolis, MN – 30 April 2021: Medibio Limited (MEB or the Company) (ASX: MEB) (OTCPINK: MDBIF), is pleased to announce its quarterly activity report and Appendix 4C for the three months ended 31<sup>st</sup> March 2021:

### Regulated Business Unit Update

*i. Sleep Analysis of Depressive Burden (“SADB”) trial (MEB-001)*

The Company continued its depressive burden algorithm development and patient recruitment for the SADB trial. The Company’s progress continues to indicate that a reliable, evidence-based automated tool that uses objective physiological measures, will assist clinicians detect depressive burden in non-psychiatric clinical settings, such as sleep clinics.

Medibio’s technology is founded on the basis that the mental health conditions of an individual is strongly linked to the autonomic nervous system, heart rate variability and sleep disturbance; and that mental illnesses are associated with some degree of autonomic nervous system dysregulation, demonstrated by changes in overnight heart rate and heart rate variability. The Company is pleased that its results to date using sleep electroencephalogram (EEG) and electrocardiogram-based (ECG) recordings are identifying biomarkers and patterns that contribute to screening for, and the identification of, significant depressive burden symptoms in patients referred to sleep clinics due to sleep disturbances.

On 3<sup>rd</sup> March 2021 the Company informed the market about the acceptance of two of Medibio’s clinical team’s abstracts at “SLEEP 2021,” the 35<sup>th</sup> annual meeting of the U.S. Associated Professional Sleep Societies (APSS) and the American Academy of Sleep Medicine.

Medibio’s abstracts presented are entitled:

- Better and Faster Automatic Sleep Staging with Artificial Intelligence; and
- Heart Rate and Heart Rate Variability During Sleep as Biomarkers for Depression.

The acceptance of these abstracts further validates the standard and quality of its clinical team’s outputs.

SLEEP 2021 is the premier world forum for the presentation and discussion of the latest developments in clinical sleep medicine and attended by worldwide expert sleep professionals. The meeting provides evidence-based education to advance the science and clinical practice of sleep medicine, disseminates cutting-edge sleep and

# ASX Announcement

Medibio Limited – 30 April 2021

circadian research, and promotes the translation of basic science into clinical practice. The conference will be held virtually on June 10-13, 2021.

*ii. Sleep Staging Software, MEBsleep*

Medibio received CE Mark approval for MEBsleep in January, which will allow commercialization in the European Economic Community.

MEBsleep is a software-only medical device that analyses Electroencephalogram (EEG) and Electrocardiogram (ECG) data collected during polysomnography to verify sleep stages and heart rate variability (HRV) in patients suffering from primary or secondary sleep disturbances. MEBsleep uses artificial intelligence, machine learning and deep learning algorithms and neural network methodology to analyse large amounts of raw data, including autonomic nervous system modulation throughout sleep stages, to highlight key information to assist the physician in understanding the patient's condition.

In April 2020 Medibio submitted a 510(k) application for MEBsleep. In December 2020, the FDA informed Medibio that, amongst other things, it required clinical data that better reflected the proposed intended use population and provided a detailed pathway as to how Medibio may achieve approval for MEBsleep. Following that guidance, Medibio commissioned an independent, in-depth review of its MEBsleep technology by the well-known and respected regulatory law firm, DuVal & Associates.

As a result of the FDA guidance and the review by DuVal & Associates, Medibio designed a new prospective clinical trial to inform a new 510(k) application. It is noteworthy that the patients participating in the MEBsleep trial will also be eligible for the depressive burden trial (MEB-001), ensuring that the MEBsleep trial will be cost-effective.

Medibio has since resolved to submit a new 510(k) application for MEBsleep, details of which may be read [here](#).

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

*iii. Corporate Health – ilumen*

ilumen, Medibio's corporate mental wellbeing software product, provides an employer rich, de-identified, aggregated data to measure and manage the mental wellbeing of its workforce, whilst providing the employee a mental wellbeing "snapshot" so they may make improvements over time. Employees identified as high risk receive a confidential, personalized notification.

During the March quarter Medibio signed the first Statement of Work agreement (**SOW**) pursuant to the Global Master Service Agreement signed with Compass Group Plc, to begin the implementation of ilumen in the UK. The SOW provided for the participation of an initial 1,000 employees for a minimum period of 12 months and marked the first stage of the ilumen roll out to the Compass UK workforce. Medibio is currently in discussion with multiple other Compass subsidiaries and will make further announcements when SOW's are executed. Compass Group companies are also advocating ilumen to its clients and is actively including ilumen in its proposals to clients globally.

Existing revenue generating programs for ilumen continue to proceed well with PwC Australia, Goodman Group and Stantec. During the quarter Stantec renewed its contract with Medibio for a further 12 months.

Although business development was hampered by COVID-19 in 2020, the interest in ilumen is strong and the Company is engaged in many meaningful conversations with prospects which will be announced in due course.

# ASX Announcement

Medibio Limited – 30 April 2021

*iv. Consumer Health – Consumer App*

Medibio's Consumer App initial testing phase commenced in January 2021. The COVID-19 pandemic, along with its many social and economic consequences, has exacerbated mental health conditions amongst the global population. In the United States, the increased stress and anxiety has adversely impacted the mental health of an estimated 53% of adults and 71% reported that they could have used more emotional support<sup>1</sup>. Medibio aims to address the increased demand for online mental health services, through the development of its Consumer App, which will be 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 rate<sup>2</sup>, underpins the functionality of the Consumer App and provides a significant point of difference in the marketplace.

The App will identify how stress is affecting the user, whether positively or negatively, considering the user's personality dimensions and emotional characteristics. Medibio's Consumer App uses objective measurements from biometric data and a psychometric assessment (which measures stress that an individual "perceives") to provide users with a holistic understanding of their stress.

In order to associate their data to an actionable program for stress management, the App will also offer cognitive behavioral exercises, educational tools and goal-setting features to help users develop solutions that work best for them. All of the recommended activities and resources are based on clinical research and validated by Medibio's clinical research partner Humanitas University in Italy and Medibio's Chief Medical Officer.

The App aims to take advantage of the market opportunity in the United States, and, in due course will be available for download in multiple regions globally through the App Store (iOS) and the Google Play Store (Android).

The second round of testing, which commenced subsequent to the end of the March quarter, may be read [here](#).

*v. Corporate and Financial Update*

The Company's cash position as at 31 March 2021 was approximately \$2.2m. During the March 2021 quarter, the Company raised \$3m (in two tranches) by way of a placement of 333,333,333 ordinary shares at an issue price of \$0.009 per share (before costs) from sophisticated, professional and other exempt investors. The Company also secured approximately \$1m via the issue of 111,111,111 ordinary shares pursuant to a Share Purchase Plan (SPP), at an issue price of \$0.009 per share (before costs). A total of \$1.3m relating to the SPP and part of tranche two of the capital raising was received post quarter end. The full details of the SPP raising may be seen [here](#).

The funds raised via the placement and SPP will enable the Company to continue the development and trials of MEB-001 and MEBsleep; undertake marketing and promotional activities for the Company's corporate wellness product,

---

<sup>1</sup> <https://www.kff.org/coronavirus-covid-19/issue-brief/the-implications-of-covid-19-for-mental-health-and-substance-use/>; American Psychological Association's Stress in America report, Feb. 2021.

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

# ASX Announcement

Medibio Limited – 30 April 2021

lumen; and accelerate the development of the Company's Consumer App in order to meet its commercial launch date of October 2021.

Total research and development and other intellectual property expenditure of \$536,000 was incurred during the March quarter relating primarily to MEB-001, MEBsleep, consumer app development and related FDA 510(k) submission processes.

Payments to related parties and their associates during the quarter was approximately A\$131,000. These payments related to Director fees and remuneration of their associates. Ms Melanie Leydin, Director and 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 Limited.

## **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).

## **Medibio Investor and Media Enquiries:**

Samantha Eng

WE Communications

T: +61 (0) 404 369 388

[WE-AUMedibio@we-worldwide.com](mailto:WE-AUMedibio@we-worldwide.com)

## 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 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	31	72
1.2 Payments for		
(a) research and development	(139)	(475)
(b) product manufacturing and operating costs	(68)	(141)
(c) advertising and marketing	(3)	(29)
(d) leased assets	-	-
(e) staff costs	(215)	(544)
(f) administration and corporate costs	(307)	(950)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	1
1.5 Interest and other costs of finance paid	(3)	(3)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	162	1,110
1.8 Other (IP expenditure)	(4)	23
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(546)</b>	<b>(936)</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	(536)	(1,310)
(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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(536)</b>	<b>(1,310)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities) *	2,727	4,244
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	(234)	(444)
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)	(32)	(100)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>2,461</b>	<b>3,700</b>

\*The \$2,727,000 figure in section 3.1 includes \$727,000 of deposits received from investors in the March 2021 period, shares for which were issued in April 2021.

<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	832	813
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(546)	(936)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(536)	(1,310)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	2,461	3,700
4.5	Effect of movement in exchange rates on cash held	30	(26)
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>2,241</b>	<b>2,241</b>

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

<b>5.</b>	<b>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	2,241	832
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>2,241</b>	<b>832</b>

<b>6.</b>	<b>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	131
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.</b>	<b>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)	-	-
7.4	<b>Total financing facilities</b>	-	-
7.5	<b>Unused financing facilities available at quarter end</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		

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(546)
8.2 Cash and cash equivalents at quarter end (item 4.6)	2,241
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	2,241
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>4.1</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: 30 April 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.