ASX Announcement

Medibio Limited – 29 October 2021

September 2021 Quarterly Activities Report and Appendix 4C

Key highlights from the quarter:

- **Sleep Analysis of depression trial moving into validation trial stage following high levels of performance;**
- **Consumer App LUCA successfully launched on 1st October as planned.**
- **Medibio's corporate mental wellbeing platform ilumen, a finalist in the Garmin Global Innovation Healthcare Awards to be held in Lisbon, Portugal**
- **New US-based members appointed to the Growth & Advocacy Advisory Board.**

Melbourne, Australia and Minneapolis, MN – 29 October 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 30 September 2021:

2021 to date has been a pivotal year for Medibio. The long-anticipated consumer app LUCA was launched. LUCA is now available on the App Store for iPhone and Google Play for Android. Both Apple and Garmin watches can connect to LUCA. And after years of research and patient trials, the Company is now leading the way to FDA approval of its clinical depression medical software device, helping health care professionals confirm their diagnosis and monitor the effects of therapeutic and pharmaceutical treatments. This lays the foundation to expand the company further as it delves deeper into the world of mental health to properly help diagnose and monitor depression. With mental health being at the forefront of conversations due to the pandemic, the Company is taking a leadership position in this space.

Top mental health experts have enthusiastically signed on to the advisory board which includes a world expert on depression and anxiety disorder, Professor Giampaolo Perna of Humanitas University in Milan, prominent US-based psychologist Elizabeth Lombardo, business development executive Mr John Mathias of MedBridge Healthcare, and mental health advocates Michael Phelps and Patrick Kennedy. While the advisory board has remained largely dormant since its formation in August 2019, the Company is excited to have such high calibre individuals involved to take the Company forward and expand its opportunities now that both ilumen and LUCA are in the marketplace.

The purpose of the advisory board is to:

- facilitate interactions with business, non-profit, media, and other professional groups and research organizations;
- assist Medibio to stay abreast of general mental health policy, political developments, emerging trends, issues, market intelligence and opportunities in mental health; and
- provide insight and advice on Medibio's go to market strategy in the US for its product offerings from time to time.

Their duties and responsibilities will include:

- maintaining an advisory partnership with the Board and providing counsel on issues raised by the Board;
- providing insight and intelligence on potential market opportunities and risks;

- providing market insight and specific knowledge on key topics and intelligence, to support Medibio's strategic goals, particularly in relation to Medibio's corporate product, ilumen and Medibio's consumer app, known as LUCA;
- providing market insight and specific knowledge on key topics and intelligence, to support Medibio's strategic goals in relation to Medibio's clinical research and development programs;
- providing market introductions, including to potential suppliers and customers;
- engaging with non-member stakeholders;
- ensuring collaboration with industry stakeholders;
- understanding the external market, including developing an understanding of the business, market and industry trends;
- identifying potential partners;
- opening and facilitating networks to advance Medibio's business and relationships; and
- such other duties and responsibilities as may be communicated by the Board from time to time.

Each of these board members have agreed to their appointments and the broad terms and conditions. Documentation is currently being finalised and once executed, the appoints are expected to be for a period of 12 months for a collective amount of 12m options over ordinary shares in the Company.

The remainder of 2021 will see new executive appointments in Minneapolis to support the FDA program and accelerate the promotional activities for both LUCA and ilumen in 2022. To this end Medibio will be committing substantial funds to marketing and sales activities for LUCA and ilumen and stepping up efforts to complete our validation trial of MEB-001 as quickly as possible. The USA is certainly open for business, and I do anticipate that Australia will soon follow.

Medibio's relationship with Garmin continues to develop and grow. It is noteworthy that Medibio has entered into a cross-promotional agreement with Garmin whereby Garmin will bundle an annual subscription for LUCA into the price of their wearable devices purchased when a user is directed from the LUCA website. Garmin has also nominated our corporate app, ilumen as one of three finalists (from a total of 63 entries) in their Global Innovation Healthcare Awards to be announced in Lisbon, Portugal. I will personally be presenting ilumen at the awards night, which will also be broadcast live to all of Garmin's global partners.

Although lead times for securing commercial contracts for ilumen have taken longer than expected (due to a large part the COVID-19 border restrictions), interest in ilumen remains strong and Medibio looks forward to being able to promote ilumen aggressively as borders open domestically and internationally. As Medibio approaches 2022 and vaccination rates in Australia continue to increase, the Company is hopeful that border restrictions will ease, and international travel will re-commence. These conditions, which impeded the company's progress in 2020 and 2021, will greatly facilitate the conduct of business in both Australia and the United States, particularly in relation to ilumen.

Clinical trial update

Sleep Analysis of Depressive Burden study (SADB) (MEB-001)

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The SADB algorithm development, known as MEB-001, is entering validation trials of the study; and to date, data analysis has demonstrated high levels of performance in overall accuracy, sensitivity, and specificity relative to the current best practice standard for measurement of depression in the US, PHQ-9. The SADB study population has now expanded to include sleep centres in Minnesota, Ohio, North Carolina, South Carolina, Florida, Missouri, and Connecticut to expedite the clinical study timelines.

The MEB-001 algorithm has been developed to utilise inputs from FDA-cleared polysomnography (PSG) systems, which are used for sleep studies to diagnose sleep disorders. The algorithm performs a parsing analysis of electroencephalogram (EEG) and electrocardiogram (ECG) biological signals to identify the likelihood of current major depressive episode in patients referring to sleep clinics for sleep disturbances. Thus far, the Company's clinical analysis has shown significant patterns of discrimination for moderate to severe cases of depressive burden.

Using physiological data (ECG and EEG) collected during a sleep study, MEB-001 utilizes machine learning algorithms to predict the likelihood that the patient is experiencing a current major depressive episode. This prediction is designed to be comparable to a PHQ-9 score >= 10, which is the clinical standard and best practice for screening for a current major depressive event. MEB-001 will report the screening result to the clinician. See graph below.

Development of Software Medical Device (MEB-001SaMD)

As a result of the success of the SADB exploratory and late feasibility phase trials, planning has now begun for the development of the cloud-based software medical device platform known as MEB-001SaMD (which incorporates the MEB-001 algorithms). Medibio will seek FDA De Novo approval for the Cloud-based Software Medical Device (MEB-001SaMD) during calendar year 2022.

MEB-001SaMD is intended to assist physicians in determining whether a patient should be referred for a more in-depth mental health evaluation. We believe MEB-001SaMD can ultimately be utilized within the USA by a primary care physician, sleep physician, neurologist, cardiologist, or ENT surgeon, as they are responsible for completing a referral to a mental health professional for evaluation. Medibio is currently in discussions with some of the largest U.S.-based medical insurance carriers to understand and confirm the clinical utility and commercial value to clinicians in the United States.

Given these developments, Medibio's clinical staff and its FDA consultants DuVal & Associates are now preparing the documentation required to accompany a request in November 2021 for a pre-submission meeting with the FDA. The purpose of such pre-submission meeting is to obtain FDA feedback on the Indication for Use (IFU), the trial design, its endpoints, the patient trial numbers, and the diversification of the patient population; it will also detail the Intended Use of the MEB-001SaMD and how it will be used in a clinical setting.

The proposed FDA validation trial is designed to compare the results from MEB-001SaMD with the results for moderate to severe depression as determined by the PHQ-9 (best practice standard for measurement of depression in the US). Medibio will propose a minimum performance of 65% to satisfy the criteria for study success. However, internal studies have demonstrated higher levels of performance at 75%. The Company estimates a total of 370 patients will provide adequate power to satisfy the two primary endpoints.

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Update on MEBsleep

On the 27th of August 2021, Medibio was scheduled to meet with the FDA regarding MEBsleep; prior to the meeting, the FDA indicated that because of MEBsleep's innovative approach, a 510(k) would not be the best regulatory pathway to regulatory clearance. Subsequent to the FDA meeting, it was concluded that MEBsleep's current design would require modification of Intended Use and possibly a new De Novo regulatory pathway prior to commercialization.

During the FDA meeting, Medibio's clinical team took the opportunity to discuss the strategy for MEB-001SaMD trial, given the similarities with MEBsleep. The FDA team provided valuable detailed feedback, which has guided Medibio's clinical team in relation to the MEB-001SaMD pre-submission meeting outlined above.

"Having carefully considered the FDA feedback, the Board of Medibio has determined that the time and resources required for a new regulatory pathway for MEBsleep is prohibitive and cannot be justified," said Medibio CEO Claude Solitario. "Further, the Board has concluded that given the promising progress of the MEB-001 algorithms, resources are best allocated to the De Novo application for MEB-001SaMD. Therefore, we are pivoting our efforts from MEBsleep's 510(k) pathway to the De Novo application for MEB-001SaMD. This targeted approach is in line with Medibio's product development strategy, and we are confident it will accelerate our progress towards commercialization."

Consumer App - LUCA

On 1st October 2021, the Company launched its first consumer mobile app to help measure, monitor, and manage stress, called LUCA. The first-of-its-kind biometric assessment tool measures sleep stress, activity stress, and cardiac stress that will allow consumers to monitor their daily stress levels through their own personal wearable device and provides science-based learning modules to help manage their stress. As a critical first step in the mental health journey, LUCA helps consumers understand how one's own personality and emotional intelligence impacts how they cope with life's stressors, while leading them to manage stress before it escalates to more harmful mental health conditions.

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, underpins LUCA's functionality and provides a significant point of differentiation in the marketplace.

LUCA was developed by the Company with over 20 years of clinical research and has been granted a U.S. patent covering the method of monitoring stress using overnight heart rate activity. As a result, the Company has developed a series of algorithms that measure sleep quality, heart rate and physical activity to arrive at an overall stress assessment. In parallel, the Company's neuroscience team identified areas of focus related to stress and developed a series of behavioural assessment tools to assist the user in understanding their stress and help back to wellness.

"We utilized our 20 years of research into the relationship between biomarkers and stress to create LUCA," *said Medibio CEO Claude Solitario*. *"With the objective biometrics collected via a wearable device, together with a*

validated Perceived Stress Assessment and our always-on virtual support system, we can help consumers confront harmful stress before it escalates. We feel LUCA will become the critical first step in the mental health journey, allowing users to see how stress materializes through biometric data, and helping them identify their own personal behaviours and characteristics to address their stress and stop it from escalating."

In September 2021, the Company signed a Wellness Sales Promotion Services Master Agreement (Agreement) with Garmin International Inc. (Garmin). The Agreement offers the Company the opportunity to bundle an annual subscription for LUCA into the recommended retail price of certain Garmin wearable devices. Medibio will also promote a dedicated Garmin landing page that promotes the bundled offer. In exchange for the sales and promotional services Garmin will return a commission to the Company from each sale.

Corporate Health program - ilumen™

Medibio continues to engage with the Federal Government in relation to mental wellbeing funding initiatives. With the support of Hon Steve Irons MP we have had meaningful discussions the Assistant Minister to the Prime Minister for Mental Health and Suicide Prevention, Hon David Coleman MP. These discussions have led to an introduction to the Department of Health team that manages the Head-to-Head platform.

We are endeavouring to travel to Canberra (border restrictions permitting) for the final sitting week of Parliament November to continue discussions with the Head to Health Digital Team of Health Department and well as potential meetings with Hon David Coleman MP, the Minister for Health, Hon Greg Hunt MP, accompanied by Hon Steve Irons MP.

In other development news for ilumen, we continue to work with our business development consultants to develop new leads. As previously mentioned, the lead times for securing commercial contracts for ilumen has taken longer than expected (due to a large part the COVID-19 border restrictions), however interest in ilumen remains strong and we will look forward to being able to promote ilumen aggressively as borders open domestically and internationally.

Discussions continue with a large international wellness provider regarding both ilumen and LUCA. Demonstrations have been provided and Medibio awaits feedback. Medibio is also awaiting on next steps with the Australian arm of a global benefits management organisation. The Company has secured a number of media opportunities for ilumen including a case study with one of its key clients, Stantec (People Matters) and has engaged with MergerMarket on two stories regarding Medibio and corporate mental wellbeing.

Corporate and Financial Update

Cash on hand at the end of the September quarter was approximately $0.88m. Total research and development and other intellectual property expenditure of $0.7m was incurred during the September quarter relating primarily to MEB-001, MEBsleep, and the consumer app development. An additional $0.55m was paid in relation to administration, corporate, staff, advertising and marketing costs.

Payments to related parties and their associates during the quarter was approximately A$0.17m. These payments related to Director fees and remuneration of their associates. Ms. Melanie Leydin, Director, 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 authorised 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 and www.asx.com.au.

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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 September 2021

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(127)	(127)
	(b) product manufacturing and operating costs	(26)	(26)
	(c) advertising and marketing	(13)	(13)
	(d) leased assets	-	-
	(e) staff costs	(180)	(180)
	(f) administration and corporate costs	(364)	(364)
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	9	9
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(701)**	**(701)**

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	(705)	(705)
	(f) other non-current assets	-	-

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**	**(705)**	**(705)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
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	(43)	(43)
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**	**(43)**	**(43)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	2,311	2,311
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(701)	(701)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(705)	(705)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(43)	(43)
4.5	Effect of movement in exchange rates on cash held	17	17
4.6	**Cash and cash equivalents at end of period**	**879**	**879**

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	879	2,311
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)**	**879**	**2,311**

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	174
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.*	**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)	(701)
8.2	Cash and cash equivalents at quarter end (item 4.6)	879
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	879
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**1.25**

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.

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?

The entity does not foresee a material adverse change in the net operating cashflows for the time being due to the impact of cost optimisation measures undertaken in conjunction with the anticipated receipt around $700,000 (subject to government clearance) in government grants and tax incentives related to the entity's research and development activities.

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?

The entity is anticipates raising further cash to fund its operations through both the completion of the claims process in respect of government grants and tax incentives related to the entity's research and development activities, as referred to in 8.6.1, and as necessary through the issuance of securities in the Company, the capability of which evidenced by previous securities issues.

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?

The entity does expect to be able to continue its operations and to meet its business objectives on the basis of the ability to raise further cash as disclosed in 8.6.1 and 8.6.2 above.

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.

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 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.