

ASX Announcement

Medibio Limited – 31 January 2022

December 2021 Quarterly Activities Report and Appendix 4C

Key highlights from the quarter:

- **Depressive burden algorithm performance continues to demonstrate a high level of accuracy.**
- **A pre-submission meeting with the FDA to agree study design and end-points confirmed for February 2nd, 2022.**
- **Discussions well advanced with trial partner Medbridge Healthcare for MEB-002 - identifying depressive symptoms in the home environment.**
- **Launched long-awaited consumer mental stress app, LUCA on 1st October 2021 in the USA.**
- **Utilizing App Store Optimization platform to improve app visibility within the app stores and increasing app conversion rates.**
- **Capital raising launched to raise up to \$5.4m (before costs) by way of Placement and Non-Renounceable Entitlement Offer.**

Melbourne, Australia and Minneapolis, MN – 31 January 2022: 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 December 2021:

Clinical trial update

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

The MEB-001 continues to demonstrate accuracy of 80% for predicting the likelihood of a current Major Depressive Episode (cMDE). The algorithm was built using the main components of the MEBSleep technology. A mental health module was added based on data collected during the SADB study. This mental health module was developed using complex statistical analyses to identify statistically significant variables that became part of the algorithm predictors.

Following FDA recommendations about geographical and clinical diversity, the current SADB study population has expanded to include sleep centres in Minnesota, Ohio, North Carolina, South Carolina, Florida, Missouri, New York, Colorado, and the West Coast. This will help to expedite the clinical study timelines. It must be noted however that due to the spread of the Covid Omicron variant and the burden of the current pandemic in the United States Health Care System, we have seen enrolments decrease across all the sleep centres. Medibio is developing several strategies, including opening more centres and incentive enrolment, to mitigate this situation as much as possible.

The MEB-001 algorithm has been developed to utilize inputs from FDA-cleared polysomnography (PSG) systems and sensors (EEG and ECG), used for sleep studies to diagnose sleep primary and secondary sleep disorders. The algorithm extracts and parses physiological biomarkers to identify the likelihood of cMDE in patients referring to sleep clinics for sleep disturbances. Using Artificial Intelligence, the Company's technology produces a probabilistic analysis to show significant patterns of discrimination for moderate to severe cases of depressive burden. This prediction is designed to be comparable to a PHQ-9 score ≥ 10 , the current best practice for screening for a current major depressive event.

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The proposed FDA validation trial is designed to compare the results from MEB-001 with moderate to severe depression as determined by the PHQ-9 (best practice standard for measurement of depression in the US). According to the prevalence and screening of depression in sleep centres, Medibio will propose a minimum performance of 65% to satisfy the criteria for study success. Medibio estimates, and has proposed to the FDA, a total of 370 patients will provide adequate power to satisfy the two primary endpoints.

The software to house the MEB-001 algorithm is now well under way. The result will be Software as a Medical Device (MEB-001SaMD). MEB-001SaMD in its final form will report the mental health result to the clinician as part of the PSG report on sleep disturbance. The MEB-001SaMD report is intended to assist physicians in determining whether a patient should be referred for a more in-depth mental health evaluation. MEB-001SaMD can ultimately be utilized within the USA by a primary care physician, sleep physician, neurologist, cardiologist, or ENT surgeon who are responsible for completing a referral to a mental health professional for evaluation.

Development of Software Medical Device for the Home Environment (MEB-002SaMD)

In the USA, the prevalence of obstructive sleep apnea is on the rise. With rising prevalence comes increased cost burdens to the health care system. Overnight evaluations to diagnose and treat sleep apnea early can bring down these costs. Traditionally, this sleep study has been performed in a fully outfitted sleep clinic. However, there are drawbacks to the in-clinic study. The first and most significant is cost; in-clinic sleep tests cost \$3,000 or more. Inconvenience is also a factor for patients. The facility may be far away, creating expense and inconvenience. Further, in the USA, it typically takes weeks or months to get scheduled in a clinic.

New technology however, allows polysomnography to be performed at home with portable monitoring devices. The in-home study usually costs less than \$600. This affordability is why payers are increasingly moving toward covering in-home sleep tests before covering in-clinic tests. Further, the requirements for an in-home sleep study are less cumbersome than for an in-clinic study, and patients can schedule them for any night that is convenient. Because no travel is involved, in-home tests are especially advantageous for the home-bound, elderly, or people with many chronic illnesses. The in-home test is administered in the comfort and privacy of the patient's bedroom, and it involves far fewer wires than with a traditional in-lab sleep study, so the patient can get a better night's sleep.

Due to the success of the MEB-001 algorithms and in recognition of the growing patient cohort moving from in-clinic sleep studies to the home environment, planning has now begun for the development of MEB-002, which will screen for Major Depressive Episode (cMDE) in patients undertaking a sleep study **in the home environment**. This study is being undertaken with Medibio's trial partner Medbridge Healthcare and is due to commence in April 2022. Medbridge has also expressed an interest in Medibio's sleep staging algorithms (MEBSleep) in addition to the Company's depression software (MEB-001).

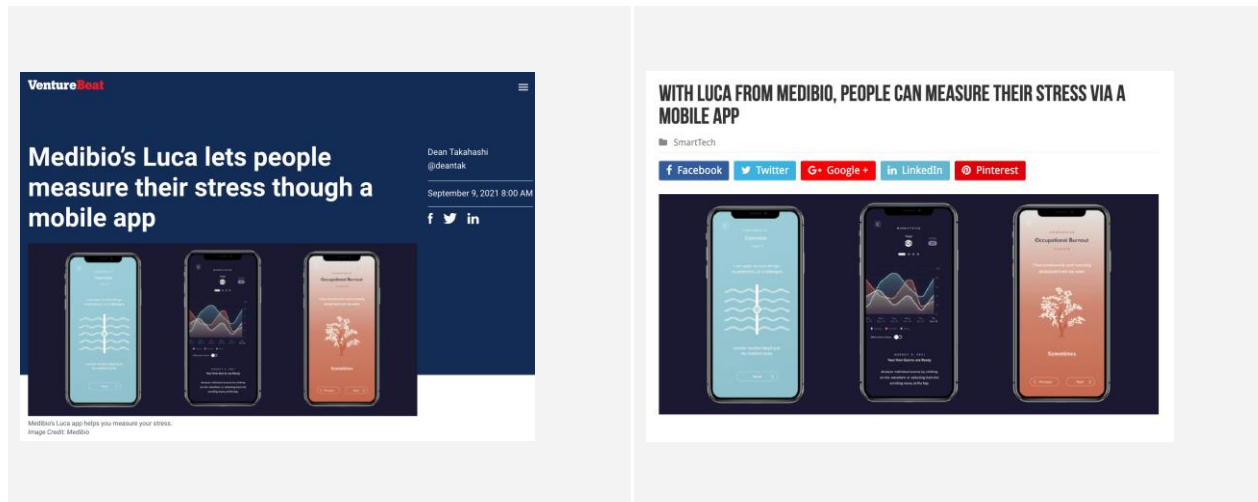
Non-regulatory Products Update – LUCA Stress App

In October 2021, Medibio launched LUCA, its consumer stress app, in the USA. US based PR company R&CPMK was engaged to facilitate the commercial launch of LUCA through a strategic, multi-pronged PR approach including earned media relations, consumer community engagement, satellite media tours (SMTs) and influencer activations. Each of these components assisted in educating and introducing LUCA to a wide variety of audiences.

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To-date, our PR efforts achieved story placements in top-tier tech outlets including VentureBeat, receiving more than 2.98 million media impressions in total, highlighted below:



Additionally, Medibio leveraged the online forum Reddit, where we successfully engaged consumers in a Reddit AMA campaign featuring Medibio's CMO, Archie Defillo MD, garnering more than 100K views.

The Satellite Media Tour that included LUCA in a Winter Wellness highlight on US news broadcasts helped reach 12 markets, garnering 156 million impressions.



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To focus on lifestyle audiences, Medibio partnered with social media personality Whitney Port to promote the benefits of LUCA. As a result, Medibio reached 250K accounts and received 7K “likes” on Instagram.

Post-launch Medibio employed direct email, organic social, and paid/sponsored social as marketing efforts. Additionally, Medibio is using an App Store Optimization platform, to help test and refine our app store content and improve placement, impression, and boost sales.

Medibio’s organic content is aimed at providing information and education about the elements and subject matter within LUCA and its paid content has a more direct Call to Action (CTA).

The conversion rate from downloads during the 14 day trial was 22.5%, which is considered an industry high. We expect this to continue as LUCA’s point of difference and additional in-app offerings resonate throughout a competitive marketplace. To date, revenue from paid installations (post the 14 day trial) continues to grow as our marketing efforts gain traction.

Additional marketing efforts that will continue to roll out in 2022 are:

- Original blog and thought leadership articles
- User engagement and surveys
- App Store refinement
- Partner offers (Garmin, Nomad)

Non-regulatory Products Update – ilumen

Medibio continues to focus its sales and marketing activities on large organisations, in particular Employment Assistance Providers (EAP) that have the network of client companies to implement ilumen at scale. In this regard, Medibio is in discussions with one of Australia’s leading EAP’s, which has the potential to take ilumen to its extensive corporate client base. The provider operates in 10 countries around the world (including the USA), in the human services industry and provides essential services on behalf of governments and the private sector across employment, health and wellbeing, communities and disability and aged care support.

During the December 2021 quarter, from a public relations perspective, Medibio sought opportunities for thought leadership and commentary on key issues surrounding mental health, sharing company announcements with stakeholders and gaining coverage for client case studies that demonstrates the value of the company’s corporate wellbeing product offering, ilumen.

Medibio also developed communication strategies around Mental Health Awareness Month to amplify coverage on specific milestones in Medibio’s journey, such as the launch of LUCA in October 2021.

Company milestones and announcements on the ASX also generated interest from the country’s most important trade media publications, with articles featured on Stockhead, The Market Herald, Simply Wall St and The Motley Fool.

Our ilumen case study with client Stantec garnered stories on the cover of The Courier’s Careers section and on business website Busy Continent. We also obtained industry commentary in a featured article in the Wellbeing issue of People Matters Magazine, an HR publication distributed within the APAC region.

ilumen was also featured in a Westpac Wire article on the positive effects of mood tracking apps in corporate environments.

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BIOMETRIC DATA GIVES INSIGHTS INTO STAFF WELLBEING

MENTAL health questionnaires have become standard in the modern workplace, as employers feel an increasing responsibility for their staff's wellbeing. Some employers are taking that commitment a step further, however, by tracking the heart rate, sleep and activity data of their teams.

Medibio's Illumen program combines questionnaire and biometric data collected from wearable devices – such as Fitbits – to give employers a more holistic insight into how their workers are feeling.

Medibio senior vice president for corporate health Jennifer Solitario says there has been increased uptake of the product since the Covid-19 pandemic – although not as much as may be expected, given the recent spotlight on mental health.

"The focus is often on short-term solutions, or solutions that aren't backed by data," she says. "Illumen provides organisations with data that they can use to monitor and manage the mental wellbeing of their workforce and assess whether mental well-being programs that they have in place are actually having an impact."

Through the program, data is provided to the employer in a de-identified, aggregated dashboard so individuals cannot be singled out.

Engineering services firm Stantec introduced Illumen for remote employees in April 2020, with about one in five opting to link their wearable device. It has since found that about a quarter of participants were experiencing moderate to severe symptoms of depression or anxiety and that 12,975 hours of productivity had been lost in the 2020-21 financial year as a result.

Stantec Asia Pacific human resources director Dr Kylie Ward says questionnaire results also showed many workers were comfortable speaking to colleagues about mental health.

"This insight reinforced our decision to invest in the Mental Health Champions program and encouraged our Champions to focus on topics around anxiety or workplace-related stress to support the wellbeing of our people," she says.



Kylie Ward, Stantec's HR director for Asia Pacific.

Corporate and Financial Update

On 15 December 2021, the Company announced a Capital Raising which would raise up to \$5.7m (before costs) (known as the ("**Capital Raising**") by way of a Placement and Non-Renounceable Entitlement Offer ("**Entitlement Offer**"). The Placement amounting to \$2.25 million is to be completed in two stages of which stage 2 will be subject to shareholder approval at an Extraordinary General Meeting on 11 February 2022 ("**Placement**"). The Entitlement Offer will be to eligible shareholders who will be given the opportunity to subscribe for one (1) new fully paid ordinary share for every three (3) existing fully paid ordinary shares held to raise up to \$3.4 million and is partially underwritten up to \$1 million.

The Placement and Entitlement Offer will be undertaken at an issue price \$0.005 (0.5 cents) per share ("**Issue Price**"). The Capital Raising will also include the issue of one (1) free attaching Option for every two (2) Shares issued under the Capital Raising with the Placement Shares subject to shareholder approval. The Company will apply for quotation for both the New Shares and Options (subject to the conditions of the ASX Listing Rules) noting that the class of Options to be issued are already an existing class of quoted Options, being MEBOC.

Cash on hand at the end of the December quarter was approximately \$1.44m. Total research and development and other intellectual property expenditure of \$0.09m was incurred during the December quarter. An additional \$0.67m was paid in relation to administration, corporate, staff, advertising and marketing costs. The Company received \$0.97m in relation to the R&D Tax Incentive initiative.

Payments to related parties and their associates during the quarter was approximately A\$0.14m. These payments related to Director fees and remuneration of their associates. Included in related party payments are payments made to Vistra Australia (Melbourne) Pty Ltd, a company associated with Me Melanie Leydin, for company secretarial and accounting services

ENDS

This announcement is authorised for release to the market by the Board of Directors of Medibio Limited.

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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.

Medibio Investor Enquiries:

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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 2021

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	34	34
1.2 Payments for		
(a) research and development	(88)	(249)
(b) product manufacturing and operating costs	(9)	(35)
(c) advertising and marketing	(55)	(68)
(d) leased assets	-	-
(e) staff costs	(165)	(345)
(f) administration and corporate costs	(439)	(769)
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	977	986
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	255	(446)
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	(891)	(1,596)
(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	(891)	(1,596)
3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	1,300	1,300
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	(78)	(121)
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	1,222	1,179
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	879	2,311
4.2	Net cash from / (used in) operating activities (item 1.9 above)	255	(446)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(891)	(1,596)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,222	1,179
4.5	Effect of movement in exchange rates on cash held	(21)	(5)
4.6	Cash and cash equivalents at end of period	1,443	1,443

Appendix 4C
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	1,443	879
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)	1,443	879

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	138
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)	255
8.2 Cash and cash equivalents at quarter end (item 4.6)	1,443
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	1,443
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: 31 January 2022

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.