

ASX Announcement



Medibio Limited – 31 July 2022

June 2022 Quarterly Activities Report and Appendix 4C

Key highlights from the quarter:

- **U.S. FDA agreed to use the MINI and PHQ-9 as the primary and secondary endpoints, respectively, for the development of the MEB-001 algorithm.**
- **Non-Executive Director Moves to Advisory Board**
- **Raised \$1.4m by way of a Placement**

Melbourne, Australia and Minneapolis, MN – 31 July 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 June 2022:

Clinical Business Unit Update

Sleep Analysis of Depressive Burden study (MEB-001)

The Company's clinical team proposed the International Neuropsychiatric Interview (MINI) as a diagnostic tool to satisfy the USA Food and Drug Administration (FDA) request for ground truth. The FDA has confirmed that the MINI can be used to support the trial clinician's diagnosis. The MINI is a structured interview, the standard MINI assesses the 17 most common disorders in mental health. The diseases investigated are the most important to identify in clinical settings. These disorders were selected based on prevalence rates of 0.5% or higher in the general population.

As the MINI is a diagnostic tool, the FDA may consider diagnosis as a clinical claim. Following the FDA's last pre-submission meeting during April, the Agency recommended moving forward with the De Novo. The FDA's recommendations consisted of making the PHQ-9 a secondary endpoint and adding the MINI as the primary endpoint.

Preparation for the pre-validation trials which commenced post quarter end (MEB-001)

MEB-001 is currently a standalone software medical device. For market purposes, it requires upgrading to a cloud-based technology that can be integrated into major sleep software analysers. By facilitating this process, we are addressing the FDA's previous questions and concerns. The Company has identified the major market-share holding companies in the sleep health environment which may benefit from the integration of The Company's technology.

Development of Algorithms for Sleep Studies in the Home Environment (MEB-002)

The Company attended and presented two scientific posters at the Sleep World Congress in Italy and conducted business development meetings with US and European companies.

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Clinical Study Update

A new study titled Sleep Analysis of Major Depressive Episode (SAMDE) was designed and approved by a central Institutional Review Board (WCG IRB - Study IRB tracking 20223322). IRB approval of the SAMDE was achieved during the quarter. The study goal is to re-train the algorithm based on the additional primary endpoint (MINI) and test algorithm overall performance, sensitivity, specificity, and negative and positive predictive values. During the quarter, preparation works commenced with a view to enrol in the study (commencing early in the September quarter) up to 17 sleep centres and a target enrolment of up to 400 full-night PSG studies. The study, subject to inherent uncertainties, is expected to be completed within 15 to 16 weeks from its commencement.

DeNovo Update

The DeNovo validation phase pre-submission filing is expected to be filled in the second quarter of 2022.

The algorithm lockdown will take place after the FDA pre-submission meeting. The Company continues development of the algorithm and software in accordance with the outcome of discussions held with the FDA. The algorithm and technology development is required to be completed by the time the Company enrolls its first patient in the clinical validation phase.

Non-Clinical Business Unit Update

LUCA Stress App

The Company is seeking additional business opportunities in the US focusing on C-suite, Pharma Companies, and mental wellness programs. Together with business partners, we are developing a new business plan focusing on a value proposition that explores new market solutions to satisfy American markets.

The Company attended the Watercooler event in London, a two-day exhibition and conference which drew in hundreds of attendees and more than a hundred experts that come together to discuss workplace wellbeing. The conference was a great opportunity for the Company to create partnerships.

American Psychiatric Annual Meeting

Medibio is one of 25 organizations invited to take part in a pre-recorded video to be included in the official American Psychiatric Association closed-circuit broadcast, providing a unique opportunity to profile the Company's key research, initiatives, and best practices in the form of a five-minute documentary feature.

Corporate and Financial Update

During the quarter, Mr. Peter Carlisle tendered his resignation from his position as Non-Executive Director and Lead Independent Director of the Company, effective on 10 June 2022, in order to focus his time and efforts on the activities of the Growth and Advocacy Advisory Board.

Mr. Claude Solitario tendered his resignation as CEO and Managing Director effective 22 June 2022 to pursue other business interests. The Company has commenced the recruitment process to fill this position and will update the market in due course.

On 22 June 2022, the Company announced that it had received commitments to raise approx. \$1.4 million capital through the issue of 923,603,673 new fully paid ordinary shares in the Company (**New Shares**) to sophisticated and professional investors at an issue price of \$0.0015 (0.15 cents) per New Share, with the offer of one (1) free attaching option for every one (1) New Share issued (**New Options**). Each New Option will have an exercise price of \$0.004

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(0.4 cents) per New Option, entitling the holder to be issued one fully paid ordinary share on exercise of a New Option, and will be able to be exercised any time up until the expiry date of 15 June 2027.

The Placement will be conducted in two tranches:

- Under Tranche 1, the Company will issue 359,499,994 New Shares under its existing placement capacity pursuant to ASX Listing Rule 7.1.
- Under Tranche 2, the remaining 564,103,673 Shares, 923,603,673 New Options and up to 27,708,110 CPS Options offered will be issued subject to shareholder approval at an extraordinary general meeting of the Company to be held on 15 August 2022.

Cash on hand at the end of the June quarter was approximately \$1.03m. Total research and development and other intellectual property expenditure of \$0.47m was incurred during the June quarter relating primarily to MEB-001 and the development, marketing and promotion for LUCA and ilumen.

The Company is in the process of reviewing and implementing cost reduction strategies to streamline its outgoings and focus the available financial resources on the successful execution of the FDA validation process.

Payments to related parties and their associates during the quarter were approximately \$0.14m. These payments are related to Director fees and remuneration of their associates.

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

58 008 130 336

Quarter ended ("current quarter")

30 June 2022

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	28	76
1.2 Payments for		
(a) research and development	-	(272)
(b) product manufacturing and operating costs	(146)	(475)
(c) advertising and marketing	(25)	(94)
(d) leased assets	-	-
(e) staff costs	(155)	(582)
(f) administration and corporate costs	(315)	(1,457)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	(1)	(2)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	(9)	972
1.8 Other (IP expenditure)	-	-
1.9 Net cash from / (used in) operating activities	(623)	(1,834)
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	(471)	(2,606)
(f) other non-current assets	-	-
2.2 Proceeds from disposal of:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-

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

	(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	(471)	(2,606)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	539	3,519
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	(115)	(293)
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	424	3,226

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	1,728	2,311
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(623)	(1,834)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(471)	(2,606)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	424	3,226
4.5	Effect of movement in exchange rates on cash held	(25)	(64)
4.6	Cash and cash equivalents at end of period	1,033	1,033

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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	1,033	1,728
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)	1,033	1,728

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)	(623)
8.2 Cash and cash equivalents at quarter end (item 4.6)	1,033
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	1,033
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.66
<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?	
The entity is currently in the process of undertaking cost reduction strategies which will reduce future expected net cashflows.	
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?	
As announced on 22 June 2022, the Company has raised approx. \$1.4m (before costs). The Placement will comprise of two tranches of which tranche 1 was completed during the quarter and tranche 2 which will raise \$846k (before costs) subject to shareholder approval.	
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 working capital if required as disclosed in 8.6.1 and 8.6.2 in conjunction with its cost reduction strategies.	
<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 July 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.