ASX Announcement

31 July 2023

Quarterly Activities Report: Pleasing clinical trial progress made with commercial rollout for Stager well advanced

Highlights:

- **Phase 1 study confirms there is a robust bidirectional relationship between mental illness and sleep – highlighting a major market opportunity for MEB and its proprietary technology**
- **Extensive work undertaken towards completion of Phase 1 trial to detect the likelihood of a current major depressive episode (cMDE) in individuals referred to a sleep clinic for polysomnography (PSG) assessment using MEB's innovative AI-backed algorithm**
- **Phase 1 tested 313 subjects across 12 sleep centres in five US states with data to be used towards ongoing algorithm development and cMDE clinical validation during H2FY2024**
- **Preliminary results reposted post quarter-end exceed the current standard of care used to screen for the likelihood of cMDE in individuals referred to sleep clinics for a (PSG) assessment**
- **Initial Phase 1 results indicated an algorithm sensitivity of 71.65%, specificity of 71.43%, Positive Predictive Value of 35.38%, and Negative Predictive Value of 92.11% when tested within the development sample**
- **Work towards Phase 2 of trial completed during the quarter with initiatives expected to commence shortly – Phase 2 to test 400 patients across 15 US sleep centres and provide additional data for regulatory approval**
- **Development of disruptive machine learning and AI-based sleep tool, Stager progress with commercial rollout pending – MEB in advanced discussions with potential customers in the US sleep health industry with four beta testing sites already identified**
- **Board and management team refocused with key appointments made to underpin US FDA regulatory pathway and technology commercialisation**
- **Company completed a Share Purchase Plan (SPP) and received total funds of $1.5m**

Perth, Australia, and Minneapolis, USA: Medibio Limited (**MEB** or the **Company**) (ASX: MEB) (OTCPINK: MDBIF) is pleased to provide the following report on activities for the three month period ended 30 June 2023 (the "quarter"). The Company progressed a number of milestones during the quarter, which have laid a strong foundation to advance its clinical trial initiatives and De Novo regulatory approval pathway in the US.

Operational overview:

CLINICAL BUSINESS UNIT:

Work towards completion of Phase 1 trial:

During the quarter, Medibio continued work towards the completion of its Phase 1 Sleep Signal Analysis for Current Major Depressive Episode study (SAMDE). The aim of the trial is to detect the likelihood of a current major depressive episode (cMDE) in individuals referred to a sleep clinic for polysomnography (PSG) assessment. There is a robust bidirectional relationship between mental illness and sleep disturbances, and depression is highly prevalent in individuals with sleep disorders. Despite this, there is insufficient depression screening in sleep clinics.

The trial was completed post quarter-end and delivered promising results which exceeded the current standard of care used to screen for the likelihood of cMDE in individuals referred to a sleep clinic for a PSG assessment.

The trial commenced in July 2022 (refer ASX announcement: 21 July 2022) and enrolled 313 subjects through 12 sleeps centres across five states in the US. Nationwide enrolment was important in demonstrating clinical and geographical diversity in the patient cohort, which is critical for regulatory approval via the US Food and Drug Administration (FDA).

Phase 1 of the trial included collection of each subject's objective biometric signals during in-lab PSG studies, self-administered Patient Health Questionnaire (PHQ-9), self-administered Mini International Neuropsychiatric Interview (MINI) assessment, and socio-demographic information.

Completion of Phase 1 yielded promising results:

Subsequent to the end of the quarter, the Company reported results from Phase 1 which highlighted the potential of its offering. The results were generated from 313 subjects. 293 participants delivered usable data for algorithm development, which includes 274 full-night studies, and 19 split-night studies.

Upon completion of circa two-thirds of all trial participants, Medibio developed a cMDE detection algorithm using a selection of predictors that demonstrated the stronger individual association with the self-administrated MINI cMDE result. The preliminary results from sleep data collected indicated an algorithm sensitivity of 71.65%, a specificity of 71.43%, a Positive Predictive Value of 35.38%, and a Negative Predictive Value of 92.11% when tested within the development sample with a cross-validation protocol.

The preliminary results for Sensitivity were seen as particularly promising with reference to current US industry standards, where data compiled by Kaiser Permanente for the U.S. Department of Health & Human Services[i] for clinician recognition of depression ranges between 21% to 76% of cases. Around half of these estimates fall above and the remainder fall below the international pooled average of 47.3%. Other studies have also reported a sensitivity of 49.3% and specificity of 81.1% for U.S. primary care providers in accurately identifying cMDE.

Measure	Description	MEB preliminary result	Current standard of care
Sensitivity	The ability for the test to correctly identify patients with the disease	**71.65%**	49.3%
Specificity	Ability to designate an individual who does not have the disease as negative	**71.43%**	81.1%
Positive Predictive Value	Likelihood that a person who has a positive test result does have the disease or condition.	**35.38%**	NA
Negative Predictive Value	Likelihood that an individual with a negative test result does not have the disease or condition	**92.11%**	NA

Statistical analysis of all Phase 1 data is ongoing, which will seek to investigate the association between the preliminary predictors and depression. This will include additional work on both full-night and split-night data to identify predicators to both study types, as well as ongoing algorithm training.

Work towards the commencement of Phase 2 trial:

Medibio also laid a strong foundation for the commencement of its second phase, which will see 400 patients enrolled over 15 US sleep centres. During the trial, clinicians will administer a MINI for each subject and provide an independent assessment of the underlying status of each subject to establish ground truth regarding current Major Depressive Episode status.

This step is necessary in preparation for the upcoming clinical validation study be an imperative part of the Company's FDA submission and upcoming clinical validation study.

Phase 2 of the trial also has the potential to increase the key measures of MEB's proprietary and innovative algorithm, when compared to the existing standard of care. The Phase 2 of the trial is expected to commence during this quarter.

NON-CLINICAL BUSINESS UNIT:

Participation in the American Academy of Sleep Medicine and Sleep Research in Indianapolis Indiana USA:

This is the annual meeting of the largest organisation on sleep medicine and research in the US. The Medibio team met with multiple researchers and providers of sleep studies from the US, as well as a number of international groups.

Many of these sleep centres and research groups were introduced to the impending release of Stager during the conference, which has provided critical feedback and allow the Company to progress business development opportunities. Several researchers have since offered to become beta site users, providing a growing sales funnel for the Company.

Development and commercial rollout of Stager:

Stager is Medibio's disruptive AI-based software solution that provides research groups with new data metrics in sleep studies. The product deploys machine learning technology and deep learning algorithms to deliver insights on the four key stages of sleep in 30 minutes, opposed to the current industry standard of around two hours. Stager has been shown to have similar accuracy to human sleep raters, which is the current gold standard. The tool provides a solution for sleep researchers to measure the objective relationship between brain waves (EEG), heart rate (ECG) and heart rate variability throughout the four sleep stages.

During the quarter, Medibio furthered the development of Stager. The Company also progressed a number of discussions with potential customers around the sale and implementation of the Stager software. Medibio is targeting a number of US sleep centres for near term deployment, which presents a large market opportunity. There are currently four research organisations expected to sign beta site testing agreements in the near term. These sites will be the initial test sites for the new software which will begin in August.

Following the initial discussions with US sleep centres and research groups, the Company also dedicated some capital towards marketing and advertising for Stager. This led to a slight increase in advertising and marketing during the quarter and is expected to assist with near term sales contracts.

Management commentary:

CEO Dr Tom Young said: *"Medibio made very pleasing progress during the quarter, which was highlighted by the promising results from our Phase 1 trial reported post quarter-end, as well as the ongoing development and marketing of our Stager product, which has the potential to generate near term revenue."*

"The Phase 1 test results, which stemmed from work during the last quarter, have highlighted the accuracy of our AI-based algorithm for the sensitivity component exceeded our expectations, and the initial indications now provide the Company with a strong framework for ongoing analysis of the phase 1 results through to the commencement of the Phase 2 trial."

"Alongside Phase 2 trial initiation, the Company is focused on advancing the commercial rollout of Stager into sleep clinics and research groups in the US. Initial discussions with potential customers are well progressed and additional updates will be made as sales contracts are secured."

Corporate and Financial overview:

Board and management optimisation:

As part of the Company's restructure, Ms Melanie Leydin resigned as a Non-Executive Director and Mr Matthew Watkins stood down as Company Secretary during the quarter.

The Company appointed Mr Stephen Buckley as Company Secretary on 17 April 2023. Mr Buckley is a director of Governance Corporate Pty Ltd, a company providing specialised governance and company secretarial services to ASX listed companies. He currently acts as Company Secretary for four other ASX listed entities.

Further, Dr Tom Young assumed the role of Executive Director, alongside his current capacity as CEO. Dr Young has continued to demonstrate exceptional leadership qualities and invaluable industry expertise as CEO. The Company intends to leverage this further over the coming quarters to advance its growth strategy.

Financial overview:

The Company completed a Share Purchase Plan (SPP) and received total funds of $1.5m. New funding was deployed towards clinical trial initiatives to pursue the De Novo regulatory pathway with the US FDA, as well as the ongoing development of Stager.

Medibio has continued to implement a stringent cost focus, which led to 46% decrease in net cash outflows during the quarter when compared to Q3 FY2023. This was underpinned by a $164,000 reduction in staff, administration and corporate costs when compared to the last quarter, as well as a $23,00 reduction in product manufacturing and operating costs compared to Q3 FY2023.

Cash on hand as at 30 June 2023 was $214,000 with the Company completing its SPP Shortfall in July and raising a further $904,000. This compares to the cash balance at 31 March 2023 of $566,000. The Board and management continue to monitor funding requirements regularly to ensure sufficient working capital is available for its clinical trial initiatives and commercial roll-out of Stager.

As per item 6 of the attached Appendix 4C cash flow report for the quarter, there were no payments to related parties and their associates of Medibio Limited.

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

ENDS

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About Medibio Limited

Medibio (ASX: MEB) (OTCPINK: 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 Perth (Western Australia) and Minneapolis (MN, USA). 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.

[i] Screening for Depression in Adults: An Updated Systematic Evidence Review for the U.S. Preventive Services Task Force. Prepared by: Kaiser Permanente Research Affiliates Evidence-based Practice Center, 2016, for the Agency for Healthcare Research and Quality, (U.S. Department of Health and Human Services).

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 June 2023

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	-	24
1.2	Payments for		
	(a) research and development	-	(41)
	(b) product manufacturing and operating costs	(3)	(380)
	(c) advertising and marketing	(30)	(89)
	(d) leased assets	-	-
	(e) staff costs	(127)	(488)
	(f) administration and corporate costs	(67)	(924)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
1.5	Interest and other costs of finance paid	-	(2)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	26	971
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(201)**	**(929)**

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	(721)	(2,258)
	(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**	**(721)**	**(2,258)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	596	2,687
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	(9)	(180)
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 (payment of lease liabilities)	(16)	(40)
3.10	**Net cash from / (used in) financing activities**	**571**	**2,467**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	566	1,033
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(201)	(929)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(721)	(2,258)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	571	2,467
4.5	Effect of movement in exchange rates on cash held	(1)	(99)
4.6	**Cash and cash equivalents at end of period**	**214**	**214**

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	214	566
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)**	**214**	**566**

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	-
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)	(201)
8.2	Cash and cash equivalents at quarter end (item 4.6)	214
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	214
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.1

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?

No. The entity continues to undertake cost optimisation strategies to manage its liquidity and future expected net cash outflows. The entity also anticipates the receipt, subject to approval, of 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?

Yes. During the quarter ended 30 June 2023, the entity raised $596,000 as part of the Share Purchase Plan. Subsequent to the quarter, the entity successfully raised $904,000 to complete a $1.5m capital raise via a share purchase plan.

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?

Yes. The entity does expect to be able to continue its operations and to meet its business objectives on the basis of the factors presented in 8.6.1 and 8.6.2.

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: 31 July 2023

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.