ASX Announcement

Medibio Limited – 31 January 2023

December 2022 Quarterly Activities Report

Key highlights from the quarter:

- **SAMDE study enrollment continues to progress across 12 sleep centers in the United States with 163 subjects and 155 useable subjects. Target for January 2023 of 200 with total of 204 useable at 102%. The total target for phase 1 is 400.**
- **Targeting Breakthrough Device Designation submission with expanding data results by end of February 2023. MEB expects to receive some FDA feedback on this submission within 60 days.**
- **Initial conversations on sleeper commercialization continue for academic and pharma research studies**
- **Reorganization of executive team and Board of Directors has begun**

Melbourne, Australia, and Minneapolis, MN – 31 January 2023: Medibio Limited (**MEB** or the **Company**) (ASX: MEB) (OTCPINK: MDBIF) is pleased to announce its quarterly activity report for the three months ended December 2022:

Clinical Business Unit Update

Sleep Analysis of Major Depressive Episode (SAMDE) Study Update

The Sleep Analysis of Major Depressive Episode (SAMDE) is the Company's regulatory platform for the recognition of Major Depressive Episode Current. A unique, revolutionary and objective measure of a mental health disorder.

Active Study sites are currently open to recruitment, both for full night and split night studies, allowing for additional clinical data to be collected and processed.

- Minnesota (2)
- Ohio (3)
- North Carolina (4)
- South Carolina (1)
- Florida (2)

Enrollment

Enrollment is currently on schedule for 155 useable subjects. The study will continue to recruit a total of 300 useable subjects and the plan is to move to phase 2 by March 15, 2023. Phase 2 will include clinician administered subjects initially totaling 100 subjects.

Algorithm Development

The MEB-001 algorithm continues to be enhanced and results continue to improve with over an additional 3,000 new data points collected in the quarter. The clinical team is analyzing more data regarding the clinical markers including opioid use disorder. The algorithm will continue to be enhanced with the addition of new data points derived from the several hundred new subjects.

Sleep Analysis of Depressive Burden study (MEB-001)

The protocol design using the International Neuropsychiatric Interview (MINI) 7.0.2 and PHQ-9 is being maintained. The study is being augmented now with a Breakthrough Device Designation submission in advance of the ongoing submission and expanded clinician data collection subjects. The BDD FDA submission is scheduled by end of February 2023 with initial FDA feedback expected within 60 days of submission.

Non-Clinical Business Unit

The Clinical development team continues to work to complete the updates, including rebranding, to the clinical APP (formerly LUCA) and is working with Elizabeth Lombardo PhD interacting her work on stress and anxiety. The new application will integrate the ability to collect biometric data, provide therapeutic interventions for stress, anxiety and insomnia as well as integrate fully into behavioral product platforms.

Timelines referred to in November 2022 AGM (click here for details) are on track per scheduled dates with sales and revenue from Stager and the new clinical APP still expected in September 2023.

Corporate and Financial Update

Grant Opportunity – "Prediction of major depressive episodes from sleep data"

Medibio and OnTime Trials, Inc. (OTT) are co applicants for a Small Business Innovation Research grant responsive to Funding Opportunity Announcement (FOA) Number PA-22-177PHS 2022-2. This grant has a total value over 2 years of USD$1.8M and the Grant award date is May of 2023. If awarded the grant, Medibio and OTT plan to use their combined expertise to conduct clinical studies across 13 clinical centers, enrolling approximately 800 subjects, to support development, validation, regulatory approval and commercialization of Software as a Medical Device for sleep disorders and depression. Medibio's AI-enabled software technologies included in this grant proposal have the potential to greatly impact the monitoring of subjects suffering with neuropsychiatric and other diseases, and to provide validated tools for increased efficiency and success of testing neuropsychiatric interventions. OTT provides software for efficiently tracking remote clinical studies. OTT's software will be used to monitor and manage enrollment during the clinical studies to assure timely completion.

Grant Opportunity – "Sleep and circadian based mechanisms influencing the trajectory of OUD outcomes"

Medibio intends to apply for a research project grant responsive to FOA Number RFA-DA-23-059, HEAL Initiative has a total value of USD$3.0M over 4 years. The grant is to be awarded in August of 2023: Sleep Predictors of Opioid-Use Disorder Treatment Outcomes Program (R01 Clinical Trial Optional). If awarded the grant, Medibio will conduct a research study designed to provide insight into potential sleep or circadian based mechanisms that influence the trajectory of OUD treatment outcomes, therapeutic targets or OUD treatment. Medibio's experience and expertise in the field of sleep research, the physiology of sleep, and conducting clinical studies involving polysomnography make the company well suited to conduct this important study.

During the quarter, the Company appointed Mr David Trimboli as Non-Executive Chair who is an experienced Chairperson and is considered independent and thus will bring an objective view to the Board in order to progress the Company's strategic objectives. The Company also continues to review its management and organizational structures to ensure it is sufficiently and efficiently resourced to achieve its business objectives.

Financial position

Cash on hand at the end of the December quarter was approximately $318k. The Company continues to closely monitor its cash position and continuously reviews funding requirements on an ongoing basis to ensure that the Company has sufficient working capital to continue to fund its business operations to meet its objectives.

Total research and development and other intellectual property expenditure of $0.52m was incurred during the quarter relating primarily in respect of the ongoing implementation and support of the current sleep study and supporting the further development of MEB-001. These expenditures include the costs associated with acquisition costs associated with sleep study participants, including investment in the infrastructure supporting the sleep centres in addition to the expansion of the sleep study and the collection and the interpretation of data received from the sleep centres to date and the ongoing assessment of the impact on the associated algorithms. The total administration, corporate and staff costs during the quarter amounted to $0.48m.

Payments to related parties and their associates during the quarter were approximately $50k. 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.

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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.

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	31 December 2022

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	-	24
1.2	Payments for		
	(a) research and development	(16)	(41)
	(b) product manufacturing and operating costs	(186)	(351)
	(c) advertising and marketing	(52)	(59)
	(d) leased assets	-	-
	(e) staff costs	(97)	(216)
	(f) administration and corporate costs	(388)	(644)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
1.5	Interest and other costs of finance paid	-	(1)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	938	938
1.8	Other (IP expenditure)	-	-
1.9	**Net cash from / (used in) operating activities**	**199**	**(350)**

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	(525)	(1,007)
	(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**	**(525)**	**(1,007)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	846
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	(10)	(80)
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)	(24)	(24)
3.10	**Net cash from / (used in) financing activities**	**(34)**	**742**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	759	1,033
4.2	Net cash from / (used in) operating activities (item 1.9 above)	199	(350)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(525)	(1,007)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(34)	742
4.5	Effect of movement in exchange rates on cash held	(81)	(100)
4.6	**Cash and cash equivalents at end of period**	**318**	**318**

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	318	759
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)**	**318**	**759**

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	50
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)	199
8.2	Cash and cash equivalents at quarter end (item 4.6)	318
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	318
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	**N/A**

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?

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?

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?

N/A

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 January 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.