

ASX Announcement



Medibio Limited – 29 April 2022

March 2022 Quarterly Activities Report and Appendix 4C

Key highlights from the quarter:

- Awaiting FDA confirmation regarding optimization of the final clinical validation trial for MEB-001.
- Planning under way for MEB-002, designed to identify depression in home sleep studies.
- Medibio invited to take part in a pre-recorded video within the official broadcast at the American Psychiatric Association's 2022 Annual Meeting in New Orleans.
- Medibio to present its latest work at the World Congress of Psychiatry in Bangkok.
- Northern Michigan University joins Medibio in a pilot program to raise awareness for LUCA as a harmful-stress prevention tool for college and university students.
- Appointed two US-based directors.
- Engaged a UK-based sales and marketing team to promote LUCA and ilumen in the UK.
- Appointed a US-based business development executive for the North America non-clinical market.
- Raised approximately \$1.68m (before costs) via an Entitlement Offer and Stage 2 Placement.

Melbourne, Australia and Minneapolis, MN – 29 April 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 March 2022:

Clinical Business Unit Update

Sleep Analysis of Depressive Burden study (MEB-001)

The MEB-001 algorithm uses EEG and ECG signals from FDA-cleared polysomnography (PSG) systems to screen for Current Major Depressive Episodes (cMDE) in patients suffering from primary and secondary sleep disorders. Using Artificial Intelligence, the Company's technology analyses patterns of discrimination for moderate to severe cases of cMDE.

Medibio's clinical team met with the FDA on the 2nd of February and 7th April 2022. The pre-submission meeting was to obtain FDA feedback on the Indication for Use (IFU), the final validation trial design, its endpoints, the patient trial numbers, and the diversification of the patient population. The validation trial that was proposed to the FDA compared the results from MEB-001 with the results for moderate to severe depression as determined by the PHQ-9 (considered to be the gold standard for screening for depression in the US, according to the United States Taskforce Guidelines).

Whilst the FDA has accepted the PHQ-9 as a primary comparator to MEB-001 De Novo submission, it has requested that a mental health diagnosis also be considered as an additional primary comparator. Medibio's clinical team has proposed a diagnostic method to satisfy the FDA's request, whilst at the same time minimizing the impact on the validation trial. The Company welcomes the inclusion of a diagnostic comparator as a significant step in the development of its De Novo application. It will provide an opportunity to amend and upgrade the IFU to a screening/diagnostic tool, which would be a considerable development in the assessment and management of mental health illnesses.

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

In the U.S., the rising prevalence of obstructive sleep apnoea has resulted in increased cost burdens to the health care system. Traditionally, the sleep studies have been performed in a fully outfitted sleep clinic, however, new technology allows polysomnography to be performed with portable monitoring devices in the comfort and privacy of the patient's own home.

Due to the performance of the MEB-001 algorithms and in recognition of the growing patient cohort moving from in-clinic sleep studies to the home environment, the Company has commenced planning for the development of MEB-002. Medibio is in discussions with a home sleep test device distributor regarding access to over 4,000 patient data sets (most with corresponding mental health assessments) to inform the development of MEB-002. This will significantly reduce the time and cost of development.

Other Developments

Medibio, in collaboration with Northern Michigan University (NMU) is currently developing a program to raise awareness of the LUCA app as a harmful-stress prevention tool amongst the student and staff population. Professor Adam Prus (Distinguished Professor & Head of Psychological Science at NMU) has agreed to circularize NMU's staff and student population to encourage participation in the pilot program, which is envisaged to take 3-4 weeks. A pilot program has commenced, the results of which will inform a commercial program that will be rolled out to other universities and colleges across the United States. The target market is a total student population of approximately 20M in over 4,000 educational institutions.

American Psychiatric Annual Meeting

Medibio will participate in the American Psychiatric Association (APA) 2022 Annual Meeting in New Orleans (May 21-25, 2022) and online (June 7-10, 2022). The APA Annual Meeting attracts the largest audience of psychiatrists and mental health professionals at any meeting in the world and showcases some of the latest ground-breaking innovations across research and patient care that are helping to shape the future of psychiatry and mental health across the globe. Medibio is one of 25 organisations invited to take part in a pre-recorded video to be included within the official APA TV 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.

World Psychiatric Conference

Medibio's Abstract entitled "Depression Prevalence in Sleep Disorders: Preliminary Result from a Polysomnography-Based Depression Screening Algorithm Development Study" has been accepted for presentation at the WPA World Congress of Psychiatry in Bangkok on the 3rd to 6th August 2022. The WPA is psychiatry's global association representing 140 psychiatric societies in 120 countries and supporting more than 250,000 psychiatrists. With its 70 Scientific Sections, the WPA promotes collaborative work in specialty areas of psychiatry. The WPA World Congress of Psychiatry's Scientific Committee's recognition of Medibio's work highlights the scientific credibility our research team has been working hard to establish.

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Non-clinical Business Unit 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.

Organic Social Content is being created by our Digital Marketing Agency for a robust monthly calendar of information and promotion. Medibio has been producing original blog articles to engage audiences. It has a team of medical and other professionals, including Patrick Kennedy through the Kennedy Forum, who believe in making Medibio's research and findings accessible to all.

Medibio's Non-clinical team is currently developing marketing and PR plans for Mental Health Month in the US and UK. Mental Health Action Day is May 19th in the UK and US Medibio will be working on a joint campaign with the Kennedy Forum. The campaign will highlight what both parties are doing for mental health and our pledges for the day.

ilumen

Medibio's sales and marketing activities continue to focus on large organisations, in particular Employment Assistance Providers (EAP) that have a network of client companies to implement ilumen at scale. The Company's focus has expanded to business development opportunities on the UK and US. Management has engaged an outsourced sales and marketing team located in the UK and operating in Europe, US and Australia. The team will secure leads to large organisations, vetted to be appropriate for a combined LUCA and ilumen offering.

Early interest in ilumen in the USA has also been encouraging. Management is in discussions with several companies in diverse industries that have shown interest in ilumen.

Other Developments

Appointment of US-based Business Development Executive

Medibio is pleased to announce the appointment of Mark Walinske in the USA as Business Development Executive (North America). Mr Walinske has 40 years of early-stage and innovation experience with 20 years in the healthcare industry. He has a deep passion for advancing organizations and technologies to reverse the rising costs of healthcare and demonstrate data-driven outcomes. He was more recently the CEO/President of Benovate LLC. (sold in early 2021 to Wellness Coaches), an innovative wellbeing and consumer engagement platform delivery company. Prior to that he was an executive at UnitedHealth/Optum in the Innovation R&D organization.

Mr Walinske is suitably qualified to promote LUCA and ilumen in North America, as well as leading the development and promotion of the university student initiative with NMU.

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Corporate and Financial Update

During the quarter, the Company appointed two new Non-Executive Directors being Mr Stephen Mitchley and Mr Matthew Mesnik who were appointed on 17 February 2022 and 2 March 2022 respectively.

Mr Mitchley is based in New York and leads Vitality Group's digital and global partner disciplines. He brings 25 years of experience and expertise in overseeing operations and technology to the Vitality Group product team. Mr Mitchley joined South Africa-based Discovery Holdings Limited, the parent company of Vitality Group, in 2000 and has led large-scale process re-engineering activities and designed and built operations for new products and services.

Dr. Matt Mesnik is a physician, business executive, health IT and medical device entrepreneur, with over 30 years of experience. He is an emergency physician and former emergency department and urgent care medical director. As an accomplished healthcare executive, he has a reputation for bringing innovative solutions to market, leveraging leadership skills, technology and developing strategic partnerships.

The Company is looking forward to utilising their extensive experience and contacts for the benefit of Medibio and its shareholders.

On 15 December 2021, the Company announced a Capital Raising which would raise up to \$5.7m (before costs) ("**Capital Raising**") by way of a Placement and Non-Renounceable Entitlement Offer ("**Entitlement Offer**"). The Placement ("**Placement**") amounting to \$2.25 million was to be completed in two stages, the second of which was subject to and received shareholder approval at an Extraordinary General Meeting on 11 February 2022. The Entitlement Offer was made to eligible shareholders who were 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.

The Placement and Entitlement Offer were undertaken at an issue price \$0.005 (0.5 cents) per share ("**Issue Price**"). The Capital Raising also included 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 which was subsequently granted. The Company applied for quotation for both the New Shares and Options (subject to the conditions of the ASX Listing Rules) noting that the class of Options were issued are already an existing class of quoted Options, being MEBOC.

On 18 February 2022, the Company completed stage 2 of the Placement issuing 190,049,250 fully paid ordinary shares raising \$950,246.25 (before costs) along with issuing 225,024,625 free attaching MEBOC options under stage 1 and 2 of the Placement announced on 15 December 2021.

On 11 March 2022, the Company announced the completion of the Entitlement Offer issuing a total of 145,889,750 fully paid ordinary shares raising a total of \$729,448.75 (before costs) along with issuing 72,944,876 free attaching MEBOC options under Entitlement Offer announced on 15 December 2021. The Company and CPS are working together on a best endeavour to place any shortfall of the Entitlement Offer.

Cash on hand at the end of the March quarter was approximately \$1.73m. Total research and development and other intellectual property expenditure of \$0.54m was incurred during the March quarter relating primarily to MEB-001 and the development, marketing and promotion for LUCA and ilumen.

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Payments to related parties and their associates during the quarter was approximately \$0.12m. 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 Vistra (Australia) 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.

Medibio Investor Enquiries:
investors@medibio.com.au

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 March 2022

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	14	48
1.2 Payments for		
(a) research and development	(23)	(272)
(b) product manufacturing and operating costs	(294)	(329)
(c) advertising and marketing	(1)	(69)
(d) leased assets	-	-
(e) staff costs	(82)	(427)
(f) administration and corporate costs	(373)	(1,142)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	(1)	(1)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	(5)	981
1.8 Other (IP expenditure)	-	-
1.9 Net cash from / (used in) operating activities	(765)	(1,211)
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	(539)	(2,135)
(f) other non-current assets	-	-
2.2 Proceeds from disposal of:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-

Appendix 4C
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	(539)	(2,135)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	1,680	2,980
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	(57)	(178)
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	1,623	2,802

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	1,444	2,311
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(765)	(1,211)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(539)	(2,135)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	1,623	2,802
4.5	Effect of movement in exchange rates on cash held	(35)	(39)
4.6	Cash and cash equivalents at end of period	1,728	1,728

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	1,728	1,444
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)	1,728	1,444

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	124
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)	(765)
8.2 Cash and cash equivalents at quarter end (item 4.6)	1,728
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	1,728
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	2.25
<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?	
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	
<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: 29 April 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.