



Quarterly ASX Update and Cashflows

Medibio Limited (ASX: MEB) (OTCQB: MDBIF)

30 October 2018

Quarterly Update and Message from Medibio Limited

Sydney, Australia and Minneapolis, MN – 30 October 2018: Medibio Limited (MEB or the Company) (ASX: MEB)(OTCQB: MDBIF), a mental health technology company provides the following quarterly update:

Key highlights from the quarter

- Announced clinical study results - showing an improvement of more than 20% to current diagnostic standard
 - Achievement of 70% accuracy, 70% sensitivity and 71% specificity results - demonstrating utility as diagnostic aide and long-term monitoring
 - Study results support the FDA DeNovo submission, with FDA clearance expected in Q1 CY2019
- Launched ilumen™ corporate health product (post quarter end)
 - Platform gives employers the ability to offer biometric analysis and objective, data-driven feedback plus mental wellness assessment to employees
 - Contract signed with large Australian employer (post quarter end)
- Advanced scientific evidence - Medibio Chief Medical Officer, Archie Defillo MD, selected to present two clinical abstracts at Mayo Clinic conference in November
- Recognized technology - Medibio named a finalist in the 2018 Optus My Business Awards in health services category
- Received \$3.1 million R&D Tax Incentive Refund (post quarter end)

Quality and Regulatory Advancement

The FDA review process continues to move forward as anticipated. Our De Novo application is in the FDA review process and our team is working with the FDA on review of our application for approval. We continue to anticipate an approval in the first calendar quarter of 2019.



Our technology offers a novel approach to psychophysiological markers of mental health and physical wellbeing, specifically designed for psychiatrists, psychologists, and general practitioners that are seeking objective measures to help diagnose and monitor depression. We are seeking to change the way mental health is viewed, by providing an objective, non-invasive, convenient means to diagnose and monitor mental illness.

Having already achieved the CE Mark from Europe and TGA clearance from the Therapeutic Goods Association in Australia, we anticipate a successful FDA approval in the U.S.

The truly innovative nature of our technology required that we use the De Novo pathway for FDA submission. Following our confirmatory study - DX04 - we presented the sensitivity, specificity and accuracy of our technology to the FDA as supportive clinical evidence for the current De Novo submission.

Scientific & Technology Advancement

Mayo Clinic Convergence Neuroscience 2018

Two clinical abstracts by Defillo et al. have been accepted for presentation as part of the Mayo Clinic Convergence Neuroscience 2018 Course. Both presentations are based on Medibio's technology, the algorithm and DX04 clinical study. Dr. Defillo will share the following abstract presentations during the event to be held on November 8-10, 2018.

1. A Machine Learning Based Approach to Identify Heart Rate Variability Patterns Serving as a Diagnostic Aid for Major Depressive Episodes.
2. A Novel Technology in Mental Health Variations in Cardio-Autonomic Function Used as Diagnostic Support for Major Depressive Episodes.

Dr. Defillio's acceptance at the Mayo Convergence Neuroscience Course is further endorsement of Medibio's scientific endeavours and is a testament to our pursuit of excellence in the field of mental health.

FDA Clinical Trial Results

We announced results from our confirmatory clinical study evaluating the accuracy of our DDA algorithm. Results showed statistical accuracy of the algorithm to detect a Major Depressive Episode (MDE). This validation is a significant achievement in the Company's development of an objective test for aiding in the diagnosis of depression in patient care. We are excited by the



findings of the clinical study and believe the results and medical needs for our technology support our FDA DeNovo application.

Key benefits of the clinical study results include:

1. Demonstration of effectiveness as an adjunctive diagnostic aide
2. Accuracy of 70% with 70% sensitivity and 71% specificity.
3. Results indicated 20-40% improvement from current diagnostic standard^{[1][2][3][4]}
4. Patent-pending algorithm provides sophisticated and accurate measurements; potential for long-term monitoring of mental disorders.
5. Study targeted general population in a normal-daily-home environment- a step closer to commercialization.
6. Generate academic work and scientific publications in t support of the FDA DeNovo submission.

The technology is a step forward in the search for objective digital biomarkers of depression and other mental illnesses supported by clinical prediction models, taking into consideration that inter-rater disagreement is common in mental health conditions.

Medical benefits of the Medibio algorithm is the improvement of diagnostic sensitivity and specificity, and reduction of under-diagnosis, as compared to patients who only received clinical assessments. The results provided further validation of Medibio's proposition that psychiatric conditions differentially affect the autonomic nervous system (ANS), resulting in anomalies of cardiac and sleep functions.

Medibio's algorithm distinguished accurately between individuals with MDE and non-depressed controls in 70%-71%. The algorithm is designed to provide mental health practitioners with an objective technology to aide in assessment of MDE. These results are superior to known depressive inter-rater agreement values that range from 0.64-0.48^{1,2,3,4}.

Following release of our results, we hosted a teleconference to discuss the findings and answer investor questions in a transparent approach for all of us to share in the clinical process. Topics included the importance of the study to Medibio's technology, a general overview of the study and results, supporting methodology, and comparison to prior studies. Participants on the call included:

- Brian Mower, CFO, Interim CEO, Medibio

- Archie Defillo, Chief Medical Officer, Medibio
- Franklyn Prendergast, M.D., Ph.D., Chairman of Medibio Scientific Advisory Board
- Marie Olseth, M.D., Medibio Scientific Advisory Board, Board-Certified Adult Psychiatrist.
- Amy Fowler, RAC, JD, Gardner Law, Medibio legal counsel focused on regulatory.
- Melissa Martinson, MS, Ph.D., President Technomics Research; statistical analysis focus.

[1] Mulsant BH., et al. Interrater reliability in clinical trials of depressive disorders. *AM J Psychiatry*. 2002 Sept: 159(9): 1598-1600

[2] Lieblich Samuel, et.al. High heterogeneity and low reliability in the diagnosis of major depression will impair the development of new drugs: *BJPsych Open* (2015) 1, e5–e7.

[3] Cairney J., et al. Evaluation of 2 measures of psychological distress as screeners for depression in the general population. *The Canadian Journal of Psychiatry* 2007 Feb: Vol 52(2).

[4] Einfeld S., et al. Inter-Rater Reliability of the Diagnoses of Psychosis and Depression in Individuals with Intellectual Disabilities: 2007 Sept: 20 (5): 384-390

Product Advancement

ilumen™ Product Launch

We have continued development of our corporate health strategy in Australia to include a program that enlists employers to become actively involved in mental health and wellness of their employees. In October 2018, we launched ilumen™, our second Corporate Health product, to coincide with Australia's Mental Health Month and World Mental Health Day.

ilumen™, a product and platform for corporate customers, gives employers the ability to offer biometric analysis and objective, data-driven feedback along with a mental wellness assessment to their employees. The upgraded platform allows employees to access and monitor this data from their personal devices, measuring and tracking biometrics through the use of wearable technology over a period of time.

Participants can proactively learn about coping strategies, resources, and personal development plans to better manage stress and strain from life and work. Employee-specific features of the ilumen™ platform include:

- Access to personalised support and education resources to help improve mental wellness
- Ability to monitor digital biometric changes and identify how and when personal lifestyle modifications influence mental wellness
- Improved biometric integration with supported Garmin and Fitbit wearable devices.

ilumen™ provides employers with access to a de-identified, aggregate-level dashboard to support informed decision-making, improved team performance, and increased employee well-



being. Many companies have health care plans in place to address physical health. Medibio's platform allows employers to extend support to cover mental health, ushering in a new era of workplace wellness.

Our advancements in the Corporate Health offering have a core focus on designing products and services to help organisations optimise workforce performance, minimise risk, and provide better care to the people that power their businesses.

A contract signed by a large Australian employer confirms the market acceptance of our corporate wellness technology. Under the terms of the contract, ilumen™ will be offered to 8,000 personnel over a six-week engagement that commenced in October 2018. The contract is valued at \$30,000 for the six-week engagement.

Medibio is also in discussions with other large organisations and are hopeful of further success in rolling out ilumen.

Optus My Business Award

We are a finalist in the Health Services Business of the Year category at the 2018 Optus My Business Awards, the premier annual event for small and medium-sized enterprises. The awards cover 28 categories and acknowledges best practice within a particular industry. Winners will be announced on 29 November 2018.

Corporate Advancement

To stabilize the Company and continue progressing the Company's objectives following the departure of the former CEO, Brian Mower was appointed as Interim CEO from 28 August 2018. Mr. Mower is also the Company's Chief Financial Officer and has been part of the Medibio team since April 2017.

The Board engaged an executive recruiting firm to lead the efforts in finding a new CEO. Peter Carlisle and Dr. Franklyn Prendergast have led our Board's involvement in the CEO search. We have seen significant interest in the position and are well advanced towards an appointment. The process includes screening candidates by the recruiting firm, interviews with the management team, individual and group interviews with our Board of Directors, a full psychological assessment, and a thorough employment history and personal background check. We are determined to get the right candidate with proven ability to advance the company, assist



in regulatory and scientific advancements, and guide the technology along the path of commercialization.

Medibio appointed Peter Carlisle as Vice-Chairman to support the Company's expansion in the US, where Peter's valuable and unique skills and background in marketing, public relations and communications, contract negotiations, and law will help the company progress with its innovative mental health platform. Mr Carlisle has been with the Company's board since June 2017.

We appointed Jennifer Solitario as Senior Vice President of Corporate Health. Ms. Solitario is a proficient leader with more than 20 years of experience in the health insurance industry and brings proven and extensive contract negotiation skills. Ms Solitario will be located in the Company's Perth office.

Lindsey Hagan joined Medibio as VP of Integrated Health Systems in September to partner with the technology and clinical teams on product strategy and lead business development initiatives. Ms Hagan has more than 13 years of sales experience working with medical device, technology, pharmaceutical, and healthcare organisations.

Quarterly Expenditure and Cash at Bank

In October, Medibio received A\$3.1 million from the Australian Taxation Office under the Research and Development Tax Incentive Program. The cash refund is related to expenditure on eligible Australian and Overseas R&D activities conducted during the financial year ended 30 June 2018.

The Company's cash position at 30 September 2018 was A\$1.5 million. During the quarter, the Company had \$0.2 million inflows and \$4.8 million outflows of cash. The cash receipts represent payments from customers and interest. Cash expenditures included A\$0.7M for legal and other costs associated with the departures of former employees and contractors of the Company. A\$4.1 million cash expenditures were used for recurring business activities, including the development and commercialization of products, business integration, and expenses incurred for regulatory filings. In addition to the receipt of the Australian R&D tax grant, the Company anticipates additional cash inflows from customer payments, other grants, and payments from partly paid shareholders. Anticipated cash available for use by the Company is A\$4.6 million.

We are mindful of the cash position and have taken certain cost reduction actions, including termination of vendor contracts and reduction in staff, to reduce net future quarterly cash



outlays while maintaining an adequate infrastructure to support organisational goals following FDA approval. Upon appointment of the new CEO, the CFO role will be transitioned to a part time role. We continue to review spending with the goal of bringing net quarterly cash spend to under \$3.0 million. Our focus will continue to be on product development, scientific research, regulatory filings, and advancing our technology in commercialisation.

About Medibio Limited

Medibio (ASX: MEB) (OTCQB: MDBIF) is a mental health technology company that has pioneered the use of objective biometrics to assist in the screening, diagnosing, monitoring and management of depression and other mental health conditions. The company was founded in Australia, with offices located in Melbourne (VIC), Perth (WA) 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.otcm Markets.com and www.asx.com.au.

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Further Information: Website: www.medibio.com.au	
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Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

Name of entity

Medibio Limited

ABN

58 008 130 336

Quarter ended ("current quarter")

30 September 2018

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	196	196
1.2 Payments for		
(a) research and development	(673)	(673)
(b) product manufacturing and operating costs	(14)	(14)
(c) advertising and marketing	(261)	(261)
(d) leased assets	-	-
(e) staff costs	(2,254)	(2,254)
(f) administration and corporate costs	(1,662)	(1,662)
1.3 Dividends received (see note 3)		
1.4 Interest received	38	38
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (GST refund)	19	19
1.9 Net cash from / (used in) operating activities	(4,611)	(4,611)

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) property, plant and equipment	-	-
(b) businesses (see item 10)	-	-
(c) investments	-	-
(d) intellectual property	-	-
(e) other non-current assets	-	-
2.2 Proceeds from disposal of:		
(a) property, plant and equipment	-	-
(b) businesses (see item 10)	-	-
(c) investments	-	-
(d) intellectual property	-	-
(e) other non-current assets	-	-
2.3 Cash flows from loans to other entities	-	-
2.4 Dividends received	-	-
2.5 Other (provide details if material)	-	-
2.6 Net cash from / (used in) investing activities	-	-

3. Cash flows from financing activities		
3.1 Proceeds from issues of shares	-	-
3.2 Proceeds from issue of convertible notes	-	-
3.3 Proceeds from exercise of share options	-	-
3.4 Transaction costs related to issues of shares, convertible notes or options	-	-
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	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of quarter/year to date	6,124	6,124
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,611)	(4,611)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	29	29
4.6	Cash and cash equivalents at end of quarter	1,542	1,542

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	679	367
5.2	Call deposits	863	5,757
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)	1,542	6,124

6.	Payments to directors of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to these parties included in item 1.2	108
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-
6.3	Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2	

Payments to directors and director related entity's for the September 2018 quarter.

7. Payments to related entities of the entity and their associates	Current quarter \$A'000
7.1 Aggregate amount of payments to these parties included in item 1.2	-
7.2 Aggregate amount of cash flow from loans to these parties included in item 2.3	-
7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2	

N/A

8. Financing facilities available <i>Add notes as necessary for an understanding of the position</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
8.1 Loan facilities	-	-
8.2 Credit standby arrangements	-	-
8.3 Other (please specify)	-	-
8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.		

N/A

9. Estimated cash outflows for next quarter	\$A'000
9.1 Research and development	(600)
9.2 Product manufacturing and operating costs	(15)
9.3 Advertising and marketing	(85)
9.4 Leased assets	-
9.5 Staff costs	(1,500)
9.6 Administration and corporate costs	(1,000)
9.7 Other	-
9.8 Total estimated cash outflows*	(3,200)

* On 15 October the Company received \$3,146,835 from the Australian Taxation Office under the Research and Development Tax Incentive Program.

10. Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	Acquisitions	Disposals
10.1 Name of entity	-	-
10.2 Place of incorporation or registration	-	-
10.3 Consideration for acquisition or disposal	-	-
10.4 Total net assets	-	*
10.5 Nature of business	-	-

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.

Sign here: 
(Company secretary)

Date: 30 October 2018

Print name: Melanie Leydin

Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
2. If this quarterly 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 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.