

Quarterly ASX Update and Cashflows

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

31 December 2017

Quarterly Update and Message from CEO of Medibio Limited

Sydney, Australia and Minneapolis, MN – 31 January 2018: Medibio Limited (MEB or the **Company**) (ASX: MEB)(OTCQB: MDBIF), a mental health technology company provides the following quarterly update and message to shareholders from Jack G. Cosentino, CEO and Managing Director of Medibio Limited:

Having joined the Medibio team almost one year ago, I am pleased we have completed a thorough assessment of the risks for the Company and commenced execution on key outcomes and deliverables that have long been communicated to the market. Over the past quarters we have worked to refine the operations of Medibio and provide the direction and communication needed to deliver value and demonstrate execution.

By bringing together a quality team alongside a strong board, we have established a strategy which mirrors both the size and scope of the healthcare sector Medibio occupies, as well as the need that we are addressing. Putting this technology into the hands of the patients in need, whilst providing the right care at the right time, every time, remains a central ethos and is core to why we remain passionate about Medibio.

We continue to build the required infrastructure to properly service the need we have identified and to source new talent to ensure we have scalable and controlled growth for the future. The entire Medibio team is focused on achieving our key deliverables with a strong focus on new product launches and associated market disruption as we roll out our strategy.

Over the past year we are pleased to have moved beyond a company focused solely on research to start actively addressing the commercialisation of Medibio. We remain confident that our new leadership and technology team, with the support of the Board, can deliver on our desire of



providing our much needed technology to the patients, clinicians and organisations that need it most.

Quality and Regulatory Update

In building quality systems and processes, the Medibio team accomplished a major milestone internally by achieving our first objective around this objective. Receiving a Certificate of Compliance, certifying that the Company's Quality Management System (QMS) complies with the requirements of ISO 13485, signifies that the Company has established a comprehensive QMS for the design and manufacturing of medical devices. ISO 13485 is a critical prerequisite to securing CE Mark and other regulatory certifications. This remains an important milestone for the maturation of the company with CE certification anticipated in third quarter of financial year 2018. The ISO certificate also includes conformance with the Canadian Medical Device Conformity Assessment System. The certificate was issued by DQS Med, the Notified Body appointed to assess Medibio's submission for CE Mark.

Additionally, the Company has put in place an internal team for regulatory and quality control to support the growing complexity of the QMS as we expand our product portfolio. We have completed our technical file and are awaiting confirmation shortly.

In regards to our FDA certification, we have now closed the pre-submission file and are heading into completion of our De Novo Application. Once our clinical study is completed we will submit the full package to FDA with their feedback from our pre-submission to inform the application.

Clinical Update

The FDA associated MB-DEPDX04 confirmatory study is now active at eight sites (six in the US and two in Australia). Study enrolment completion is anticipated near the end of the third quarter of financial year 2018. We were pleased to have the US Veterans Affairs hospital located in White River Junction, Vermont (USA) join the study.

The Company's treatment monitoring studies are demonstrating good progress. MB-DEPMON02 - Electroconvulsive Therapy (ECT) compares longitudinal physiological data with serial, structured clinical assessments for subjects undergoing ECT for depression. Eight of the ten subjects enrolled as part of the initial phase have completed the study thus far. MB-DEPMON01 (Pharma) study has been initiated and pending the first subject enrolment. The study is similar in design to the ECT



study, but will follow individuals initiating standard pharmacologic therapy for unipolar and bipolar depression. Finally, the investigator-initiated Monash Transcranial Magnetic Stimulation (TMS) study has enrolled sixteen subjects thus far and uses Medibio technology to characterise progress of individuals undergoing TMS and the effects of TMS treatment on heart-rate and circadian patterns.

In addition, we are actively preparing to initiate enrolment in a study for the research and validation of a consumer screening product for mental wellness. Individuals will complete clinical assessments and use a standard consumer wearable device for around 30 days. Physiological data collected will be processed through Medibio's analytics platform and compared with the results from clinical assessments.

The company is also continuing to support investigator-initiated studies to expand the use of the Medibio analytics platform to multiple other clinical indications, including anxiety, post-traumatic stress disorder, bipolar, and schizophrenia.

Research and Development

This quarter has been transformative for our technology platform, products and algorithms. We have completed a comprehensive product roadmap for the platform, data science approach, and applications development. This roadmap drives our strategy of agile development and kicked off our product development cadence and versioning. Our team is being assembled while development of both the platform and products are in the development-to-production stage. This roadmap will be included in our upcoming board approved strategy plan that will be shared with the market in due course.

Driving this initiative we included a major addition to our internal capabilities with the addition of Jeremy Schroetter to the Medibio leadership team. Prior to joining Medibio, Jeremy was with Qualcomm Life as Senior Director of Engineering where he led teams building IoT platforms for medical devices and technical leadership for acquisitions such as Capsule and the UnitedHealthcare Motion program. His career in technology has also included the roles of Chief Technical Officer for the Medical Device and Healthcare business unit at GlobalLogic, program management for Park Nicollet and Prime Therapeutics and various leadership roles at Medtronic developing software for implantable medical devices. He graduated with a Bachelor of Science in Biomedical Engineering from Case Western Reserve University and a Master of Business Administration in Healthcare Information Technology from the University of St. Thomas.



In addition, we have recruited five data science and software development engineers. This core team replaces several contract positions that had been consulting for the Company. Having an internal team in place allows Medibio to move more quickly and work closely with the corporate development team to ensure future customers are receiving the right products at an expedited date.

Also completed during the quarter were the issuance of two additional patents. Our Intellectual Property (IP) position is critical as our technology is both disruptive in empowering the patients as well as intending to redefine the current standard of care toolkit. We intend to increase our IP position aggressively through the following quarters and will keep the market aware when our provisionals move to fully formed approvals.

Finance & Administration

The company continues to progress in transitioning the business by internalising roles and responsibilities from those that were previously outsourced to contractors. This included the internalisation of positions in technology, data science, quality and regulation during the quarter.

Quarterly Expenditure and Cash at Bank

The Company's cash position at 31 December 2017 was A\$15.1 million. During the quarter, the Company received a one-time milestone payment of A\$0.2 million from an intellectual property assignment contract related to its former pesticide business. The company also received A\$0.3 million of cash upon exercise of stock options in the quarter. On the 13th of October 2017, the Company announced the completion of a heavily oversubscribed institutional placement for A\$13.9 million to accelerate commercialisation. Net of fees, the placement provided the Company with approximately A\$12.9 million available cash. The Company also received a refund of approximately A\$3.3 million from the Australian Taxation Office under the Research & Development Tax Incentive Program for the current financial year. We also anticipate receiving A\$1.4 million from future exercise of options and partly paid shares. Available cash over the next 12 months is anticipated to be A\$16.5 million.

Total cash used during the quarter was approximately A\$3.6 million for recurring business activities. The Company also had approximately A\$1.3 million cash payments for non-recurring activities including the capital raising and payment of historical liabilities. The expenditures reflect clinical trials, research, product development and administrative activities to advance the company's technology. Quarterly expenditure is expected to increase over time as we conduct



clinical trials, product development, regulatory filings, and marketing activities associated with advancing our technology toward commercialisation, including CE Mark and FDA submissions.

Corporate Development

Medibio is working on continuing to establish collaborative partnerships to leverage existing platforms and strong existing distribution networks. Current partnerships include the recently announced Striiv agreement with further partnerships anticipated to be announced in the near term. Associated revenue from these agreements will be disclosed to the market as and when the Company has clear visibility of user takeups and associated recurring revenue streams.

In addition, we continue our collaborative agreement with Otsuka and have extended the contract and are internally targeting to formally present to Otsuka in late Q3 to early Q4 to discuss outcomes and further potential collaboration.

Scientific Advisory Board

Medibio is in the process of establishing a Scientific Advisory Board that will be led by Board member Dr. Franklyn Prendergast and our Clinical Research Director Meredith Mundy.

Investor Relations

On the 13th of October 2017, we announced the completion of a heavily oversubscribed institutional placement, in which the Company received firm commitments to raise \$13.9 million via the placement of 38,736,640 ordinary shares at a price of \$0.36 per share. The placement was conducted in a single tranche using the Company's existing placement capacity under ASX listing Rules 7.1 and 7.1A. The funds will allow the Company to build out organisational infrastructure for product commercialisation. As well as establishing requirements and testing of current products and products under development, to explore future market verticals, develop the technology platform and infrastructure to support commercialisation, and position the Company for regulatory approvals on future products.

Closing

This quarter has been transformative as we are beginning to build the required structure around the business for long-term growth. As we are rapidly moving towards an upcoming product launch, we are securing partners for both integration and distribution. By the end of the third quarter of financial year 2018, Medibio expects to provide a Board approved strategic plan alongside an updated presentation for the market.



Warmest Regards and Be Well,



Jack G. Cosentino
Managing Director & CEO

Summary of matters previously announced during the Quarter

- Agreement with Mayo Clinic
- Agreement with Otsuka Pharmaceutical
- Completes oversubscribed institutional placement
- R&D Tax Incentive Refund received
- U.S. Veterans Affairs joins FDA study
- Mayo Clinic Collaboration on Depression Technology
- ISO 13485 Certification

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), and U.S. offices in 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 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 Quarter ended ("current quarter")		
58 008 130 336	31 December 2017	

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	4	5
1.2	Payments for		
	(a) research and development	(1,986)	(3,102)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(374)	(409)
	(d) leased assets	-	-
	(e) staff costs	(1,257)	(1,859)
	(f) administration and corporate costs	(1,319)	(1,910)
1.3	Dividends received (see note 3)		
1.4	Interest received	15	20
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	3,267	3,267
1.8	Other (GST refund)	-	115
1.9	Net cash from / (used in) operating activities	(1,650)	(3,873)

⁺ See chapter 19 for defined terms

¹ September 2016

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6months) \$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	226	226
	(e) 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	226	226

3.	Cash flows from financing activities		
3.1	Proceeds from issues of shares	13,945	13,945
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	300	850
3.4	Transaction costs related to issues of shares, convertible notes or options	(1,045)	(1,045)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(13)	(13)
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	13,187	13,737

⁺ See chapter 19 for defined terms 1 September 2016

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6months) \$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	3,312	5,010
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,650)	(3,873)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	226	226
4.4	Net cash from / (used in) financing activities (item 3.10 above)	13,187	13,737
4.5	Effect of movement in exchange rates on cash held	(4)	(29)
4.6	Cash and cash equivalents at end of quarter	15,071	15,071

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	714	870
5.2	Call deposits	14,357	2,442
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)	15,071	3,312

Payments to directors of the entity and their associates	Current quarter \$A'000
Aggregate amount of payments to these parties included in item 1.2	489
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	
	Aggregate amount of payments to these parties included in item 1.2 Aggregate amount of cash flow from loans to these parties included in item 2.3 Include below any explanation necessary to understand the transaction

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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	7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2	

8.	Financing facilities available Add notes as necessary for an understanding of the position	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)	-	-
0 1	Include helew a description of each facilit	v above including the lander	interest rate and

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.

9.	Estimated cash outflows for next quarter	\$A'000
9.1	Research and development	(2,300)
9.2	Product manufacturing and operating costs	-
9.3	Advertising and marketing	(300)
9.4	Leased assets	-
9.5	Staff costs	(1,500)
9.6	Administration and corporate costs	(800)
9.7	Other	-
9.8	Total estimated cash outflows	(4,800)

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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		

Additional Information

In October 2017 the Company raised \$13.9 million (before issuance costs) via the placement of 38,736,640 ordinary shares at a price of \$0.36 per share.

Also, in October the Company received approximately \$3.3 million in R&D rebates.

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Sign here:	(Company secretary)	Date: 31 January 2018
Print name:	Robert Lees	

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.

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⁺ See chapter 19 for defined terms