

# Quarterly ASX Update and Cashflows

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

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**30 April 2018**

## Quarterly Update and Message from CEO of Medibio Limited

**Sydney, Australia and Minneapolis, MN – 30 April 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.

### Key highlights from the quarter

- ISO 13485 Certification in January 2018 with CE Mark expected imminently
- Completed enrollment of MB-DEPDX04 FDA study
- Launched an app-based limited release product available to select groups on the iPhone App Store working with certain devices, including the Apple Watch
- Filed for 16 new patent applications during the year to further strengthen the Intellectual Property of the Company
- Established an industry leading Scientific Advisory Board headed by Dr. Franklyn Prendergast and newly appointed Chief Medical Officer, Dr. Archie Defillo
- Acquired Vital Conversations establishing Medibio Corporate Health division

### Quality and Regulatory Update

The Company continues progressing the quality and regulatory segment of the business with the recent achievement of ISO 13485 certification, 100% conformity of technical file review, and indication that CE Mark is expected imminently. In addition, the Company closed out enrollment of our FDA study.

#### **CE Mark**

The Company received ISO 13485 Certification in January 2018 and has been working towards obtaining CE Marking for its product. We have prepared and submitted our technical file for review by the notified body. The purpose of the technical file review is to demonstrate compliance with the essential requirements of the relevant European product directives. The notified body has reported to the Company that the technical review is complete with 100% conformity and no outstanding matters. We are actively working with the notified body to finalize and issue the CE Mark. The notified body is responsible for issuing the CE Mark and has indicated that we should expect CE Mark imminently.



### ***Food and Drug Administration (FDA) Submission***

Medibio completed the enrollment of all participants in the MB-DEPDX04 FDA study that was initiated in September 2017. The study includes clinical sites located in both the United States and Australia with a total enrollment of 271 subjects. The next stage of the study will include close-out activities and data analysis of completed subjects.

Medibio will also be investigating the opportunity to leverage our foundational technology work along with the MB-DEPDX04 data to seek clearance for a Medibio Mental Health Monitoring Platform (MHM). The basis for this addition is the overwhelming interest of mental health clinicians, some of which were significant contributors in our clinical study, in a monitoring tool for their patients. The MHM platform would be designed to provide an infrastructure for physicians to review objective data in the clinical evaluation throughout the treatment and management phases. The Company has commenced formal engagement with the FDA on this potential application of our technology.

We anticipate that the MHM tool will vastly improve the quality of service and patient management that clinicians can provide, thereby improving outcomes for those suffering from mental health disorders. By adding tools available to clinicians, we will be better positioned to provide an end-to-end solution for mental health monitoring and management at all stages of the patients' care continuum.

### **Product and Technology Update**

Medibio continues progress on product development and on advancing its technology with product launches, patent filings, and assembling a Scientific Advisory Board.

#### **App-based Limited Release Product for Apple Watch**

A controlled release of the Company's app-based product has recently been made available to select groups on the iPhone App Store. The app is being used in programs by a select group of users with specific devices and an authorised program code. The app works in conjunction with certain devices, including the Apple Watch, that record heart rate, activity, and posture data. Following the limited release phase, the Company is anticipating making an app-based product available to consumers.

#### **Corporate Health Product**

Final testing is nearing completion on our first commercially available product that plugs into our Medibio Logic platform. This program, launching May 1st, allows corporations and insurance companies to enroll their populations and provide unique insights into individual and organisational mental health in support of improved health and performance.



### **Consumer Health**

Development of new applications are in process for consumer health products. Requirement documentation has been internally created and external consumer research has been conducted. These products are designed to use inputs taken initially from Garmin, Fitbit and Apple wearable devices for first launch slated in early fiscal year 2019.

### **Integrated Health**

Products for integrated health system customers will be developed and introduced as regulatory approvals are received and contractual relationships established.

### **Patents**

A key investment for the Company is securing and maintaining our patent portfolio. Over the course of the year, the Company has lodged 16 patent applications.

### **Scientific Advisory Board**

The scientific advisory board has been assembled. External members include the following: Martin Chapman, MBBS; Joel Ehrenkranz, M.D.; Mark A. Frye, M.D.; Lawrence Hunter, Ph.D.; Wallace Mendelson, M.D.; Marie Casey Olseth, M.D., and Giampaolo Perna, M.D., Ph.D. Internal members include Archie Defillo, M.D.; Franklyn Prendergast, M.D., Ph.D., and Peta Slocombe, M.S.

The Medibio Scientific Advisory Board (SAB) will advise the board of directors and executive leadership team on scientific matters involving the Company's advancing research, product development, interactions with academic and other outside research organizations, and the acquisition of technologies. The SAB will assist directors and management to stay abreast of industry and mental health research developments, new technologies, and anticipate emerging concepts and trends in mental health, to help keep Medibio well informed when committing its resources.

The SAB will also advise the board on scientific matters involving the safety and effectiveness of the Company's marketed products and will assist leadership to exercise reasonable oversight of product safety and medical risk management.

### **Corporate Development**

Medibio has progressed discussions with several large, global entities that have expressed various interests in business development relationships utilizing the Company's products, technology, know how, and patent portfolio.



### **Corporate Health Division**

Medibio executed on the acquisition of Vital Conversations at the beginning of March and completed the acquisition in mid-April. Integrating Medibio's objective mental health technology platform with Vital Conversations knowledge, experience and market position, enables the development of a unique comprehensive corporate health product that offers unique insights into individual and organisational mental health to support corporations' efforts to improve health and performance.

Medibio's objective measurements of mental health empowers organisations to better understand their individualised workforce above standard population information. The objective data empowers organisations to go beyond satisfaction surveys to identify which programs or initiatives are most effective.

A product launch in the Corporate Health business unit is scheduled for May 1, 2018. Our team is actively engaged in securing annualized subscription contracts for products and services with multiple entry points tailored to organisational need. Subject to program design, pricing is expected to range between \$15-\$45 per user. The newly established business unit will aim to provide organisations with cost savings by reducing the burden of mental health conditions on individuals and organisations. The Company is working on providing ongoing check-in programs and a recurring corporate mental health assessment and management program to be provided to corporates on an ongoing basis.

### **Otsuka Agreement**

The agreement between Otsuka and Medibio has progressed through several phases of the agreement, as Medibio continues to provide its advanced proprietary analytic technology to Otsuka clinical data for development of products. Under the terms of the agreement, Medibio receives payments for services provided as contractual phases are completed.

### **Management Team Update**

Over the quarter the business appointed Dr. Archie Defillo as Chief Medical Officer and appointed Jeremy Schroetter as Chief Technology Officer.

Archie Defillo, M.D. has over 25 years of clinical experience with neurological diseases. For the past 13 years his efforts have been focused in neurological research. His research interests include cerebrovascular, stroke, neuro-trauma, brain oxygenation, metabolism and autonomic dysfunction.

Jeremy Schroetter has over 20 years of experience in managing technology teams, building platforms, and software development and data science. Most recently, he was with Qualcomm Life where he led teams building IoT platforms for medical devices and



technical leadership for acquisitions such as Capsule and the UnitedHealthcare Motion program. He has also held leadership roles at GlobalLogic, Park Nicollet, Prime Therapeutics, and Medtronic.

The Company also welcomed Peta Slocombe, M.S. to the role of VP of Corporate Health following the acquisition of Vital Conversations. As a fully registered Psychologist, member of the Australian Psychological Society and a registered National Health Practitioner, Peta brings over 20 years' experience alongside her team, which has over 200 combined years of psychology practice.

### **Clinical Update**

Medibio continues to invest in ongoing clinical studies and technology to support our Research and Development, including studies with The Melbourne Clinic, The Mayo Clinic, and Monash University.

***The Melbourne Clinic ECT Monitoring Study*** - The Melbourne Clinic has completed the initial phase of enrollment in a single-arm study of participants undergoing electroconvulsive therapy (ECT) for depression. The speed of response to ECT provides a unique look at the identification of circadian pattern changes as a treatment response.

***The Mayo Clinic Pharmaceutical Monitoring Study*** - The Mayo Clinic is now enrolling subjects in a three-arm study for participants with unipolar or bipolar depression, participants receiving pharmaceutical therapy and a group of non-depressed, control participants. This study will follow subjects over a two month period of treatments. The study will also look to identify unique patterns that may help to further distinguish unipolar and bipolar depression at both the diagnostic and treatment response levels.

***Monash University Study*** - Transcranial Magnetic Stimulation (TMS) investigator-initiated 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.

***PHI Project*** - Previously reported in April 2017, Medibio entered into an agreement with the purpose of exploring clinical diagnostic products for the paediatric age group. No action has been taken by Medibio on this study. Internal review of this agreement, as well as other legacy agreements, is being done to assess both feasibility and Company interest against current strategy and deliverables.

## **Quarterly Expenditure and Cash at Bank**

The Company's cash position at 31 March 2018 was A\$11.6 million. During the quarter, the Company received payment for the first installment work performed under the agreement with Otsuka Pharmaceutical. The Company also received A\$0.1 million of cash upon exercise of stock options in the quarter. Available cash over the next 12 months is anticipated to be A\$13.5 million.

Total cash used during the quarter was approximately A\$3.5 million for recurring business activities. The expenditures reflect clinical trials, research, product development and administrative activities to advance the Company's technology. Quarterly expenditure is expected to increase in the coming quarter as we begin commercialisation and continue investment in clinical trials, product development, regulatory filings, and marketing activities associated with advancing our technology in commercialisation.

## **Closing**

This quarter has been pivotal for Medibio and its future. The proper foundation is in place and we are ready to show the world the products that will advance Medibio into a new phase of our business. The entire organization and board have been, and continue to be, focused on a clear strategy. Through commitment to exceptional product quality and operational excellence, we work towards transforming mental health care delivery.

Warmest Regards and Be Well,



Jack G. Cosentino  
Managing Director & CEO

*Medibio will be providing an audio webcast presentation on the quarterly cashflow results on Friday May 4 at 10am (AEST) on the below details.*

*Australia: +61 3 8488 8990*

*United States: +1 562 247 8421*

*Access Code: 386 825 244*

*URL: <https://attendee.gotowebinar.com/register/6839355240278298625>*

*After registering, you will receive a confirmation email containing information about joining the webinar.*



Please note that all questions can be submitted via the following email address on [investors@medibio.com.au](mailto:investors@medibio.com.au) and will be addressed throughout the call or specifically at the end of the call if required.

A replay of the webcast will be available after the event and accessible via the webinar address above.

### **Summary of matters previously announced during the Quarter**

- ISO 13485 Certification
- Resignation of Adam Darkins as Director
- Peter Carlisle appointed as Director
- Agreement with Striiv to accelerate commercialization
- Acquisition of Vital Conversations

### **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 now 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.otcmarkets.com](http://www.otcmarkets.com) and [www.asx.com.au](http://www.asx.com.au).

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<b>Further Information:</b> Website: <a href="http://www.medibio.com.au">www.medibio.com.au</a>	
<b>Medibio Shareholder Enquiries:</b> Stephanie Ottens Investor Relations Director Medibio Limited <a href="mailto:stephanie.ottens@medibio.com.au">stephanie.ottens@medibio.com.au</a> T: +61 434 405 400	<b>Australian Media Enquiries:</b> Peter Taylor NWR Communications <a href="mailto:peter@nwrcommunications.com.au">peter@nwrcommunications.com.au</a> T: +61 (0) 412 036 231

## 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")**

31 March 2018

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (...9...months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	61	66
1.2 Payments for		
(a) research and development	(1,255)	(4,357)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(269)	(678)
(d) leased assets	-	-
(e) staff costs	(1,455)	(3,314)
(f) administration and corporate costs	(754)	(2,619)
1.3 Dividends received (see note 3)		
1.4 Interest received	6	26
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	3,267
1.8 Other (GST refund)	107	222
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(3,559)</b>	<b>(7,387)</b>

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (...9...months) \$A'000</b>
<b>2.</b>	<b>Cash flows from investing activities</b>		
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
	(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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>-</b>	<b>226</b>
<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of shares	-	13,945
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	50	900
3.4	Transaction costs related to issues of shares, convertible notes or options	-	(1,045)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	(13)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>50</b>	<b>13,787</b>

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (...9...months) \$A'000</b>
<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of quarter/year to date	15,116	5,010
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,559)	(7,387)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	226
4.4	Net cash from / (used in) financing activities (item 3.10 above)	50	13,787
4.5	Effect of movement in exchange rates on cash held	(13)	(42)
<b>4.6</b>	<b>Cash and cash equivalents at end of quarter</b>	<b>11,594</b>	<b>11,594</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	198	714
5.2	Call deposits	11,396	14,402
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>11,594</b>	<b>15,116</b>

<b>6.</b>	<b>Payments to directors of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to these parties included in item 1.2	187
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	

<b>7. Payments to related entities of the entity and their associates</b>	<b>Current quarter \$A'000</b>
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	

<b>8. Financing facilities available</b> <i>Add notes as necessary for an understanding of the position</i>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
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.		

<b>9. Estimated cash outflows for next quarter</b>	<b>\$A'000</b>
9.1 Research and development	(1,500)
9.2 Product manufacturing and operating costs	-
9.3 Advertising and marketing	(400)
9.4 Leased assets	-
9.5 Staff costs	(1,850)
9.6 Administration and corporate costs	(950)
9.7 Other – Acquisition	(400)
<b>9.8 Total estimated cash outflows</b>	<b>(5,100)</b>

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**

On 12 April 2018, the Company completed the acquisition of Vital Conversations for approximately \$500,000 through cash and shares.

Sign here:  .....  
(Director/Company secretary)

Date: April 30, 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.