

# Quarterly ASX Update and Cashflows

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

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**31 July 2018**

## Quarterly Update and Message from CEO of Medibio Limited

**Sydney, Australia and Minneapolis, MN – 31 July 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

- Lodged FDA De Novo application post quarter end
- Received CE Mark and TGA clearance
- Acquired Vital Conversations
- Launched Corporate Health product and platform
- Announced first Corporate Health clients and contracts including Jacobs Engineering, St. John of God Healthcare, Rio Tinto and others
- Received scientific publication
- Confirmed release of Medibio product and platform on Apple and Fitbit platforms
- Held first Scientific Advisory Board meeting headed by Dr. Franklyn Prendergast and Chief Medical Officer, Dr. Archie Defillo



## **Quality and Regulatory Update**

The real story of reaching regulatory milestones is that with each geographical region that opens to us, we have millions more lives to save and change with our technology.

For example, we will place new tools in the hands of general practitioners, who are the front line of diagnosing and treating depression, but whose status quo success rate for diagnosing depression is dramatically low at 33-50%. Our success rate is over 80%. That is a number that will change the world, as we provide convenient, non-invasive, objective means to diagnose and monitor mental illness.

Along with the many individuals of the world who will benefit from our technology, each country or region has government agencies and private entities that will be interested in adopting our powerful solutions to address the mental healthcare epidemic in their populations.

### **European Region**

We now have a passport for the European marketplace with the attainment of the CE Mark, which will allow us to serve the mental health needs of the 500 million residents living in the 32 countries of the region. In pursuit of the CE Mark, we successfully submitted our technical file, worked with our notified body to achieve compliance, and established the required Quality Management System, which will increase efficiency and enhance product quality.

### **Australia**

We attained TGA clearance from the Therapeutic Goods Association and look forward to bringing additional products to the country where our company was founded and the millions living there who need our help. With significant success already achieved in Australia by our affiliation with Australia's Biggest Mental Health Check-in, and the acquisition of Vital Conversations, we anticipate continued wins in this market.



## **The United States**

The truly innovative nature of our technology required that we use the De Novo pathway for FDA submission. After compiling an impressive collection of research confirming the accuracy of our technology, meeting with the FDA, and progressing through the various preliminary stages, we reached a major milestone for the company in submitting to the FDA for approval on Friday, July 13. We anticipate attaining clearance by the end of calendar year 2018, and look forward to serving the needs of the 325 million people who live in the U.S.

## **Scientific Publication Supporting Medibio**

Our Chief Medical Officer, Archie Defillo, received publication for "Physiological Differences between Mood Disorder Phenotypes Based on Heart Rate Variability" in the internationally peer-reviewed journal *EC Neurology*. While we have seen the accuracy of our data science replicated by research institutions worldwide, we expect publication in the *EC Neurology* journal will lead to greater awareness of our ground-breaking discoveries and create a further proliferation of interest among psychiatrists, hospitals, and research institutions in Medibio's pioneering of objective-based mental health science.

## **Product and Corporate Development Update**

In addition to placing our clinical decision tools in the hands of general practitioners and psychiatrists, our ongoing mission involves empowering individuals to achieve self-awareness of mental states and take action to become well and stay well. Users of our Corporate Health, Consumer Health, and Integrated Health apps and the associated wearable technology obtain objective insight into their own mental health on an ongoing basis, in combined use with our subjective-assessment system, which evolved from the acquisition of Vital Conversations and the hugely popular Australia's Biggest Mental Health Check-in.



Over 20 million Apple Watches will sell in the current financial year. Fitbit has over 25 million active users and Garmin is highly popular as well. Estimates suggest that smartwatch sales will double in the next 5 years. Consumers are more and more getting in sync with themselves, tracking their own physiology and using the data to improve performance and wellness. We expect the self-care revolution will embrace what Medibio has to offer.

### **Corporate Health Program**

Following upon the acquisition of Vital Conversations, we have continued development of our corporate health strategy to include a program that enlists employers to get involved in the mental health and wellness of employees. With growing employer awareness of mental health concerns, and mental health issues being one of the top causes of work-related absence and declines in productivity, we are engaging corporations to embrace a win-win solution and sign up for our Corporate Health Program. We launched our first product in the Corporate category in May 2018.

The app provides confidential insight to individual employees based on their biometrics and results of subjective check-ins. Additionally, the corporation has access to an anonymized, company-wide or department-specific dashboard view of the mental health of the workforce. 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 employee.

We are actively honing and perfecting this offering, and have signed up major clients already, including Jacobs Engineering, St. John of God Healthcare, Rio Tinto, and others.

### **Consumer Health**

We are currently developing new applications for the Consumer Health program and look forward to bringing objectivity to the growing popularity of self-care technology. We have big plans in the works for our Consumer program and first launch is slated for early fiscal year 2019. Internal and external consumer research is ongoing.

## **Integrated Health**

For physicians, being able to monitor the real-time effects of psychiatric treatment on patients has never been possible during outpatient care, where most mental illness is treated. This has been a massive omission in mental health care that we will provide for. The Integrated Health program creates the opportunity for the doctor to see what is happening in the mental states of the patient every day while the patient is away from the treatment center or doctor's office, and vastly improve outcomes for every type of mental health care. The patient will also be able to keep track of his biometric data, and engage in dialogue with his physician through the app. We are developing this program as we await regulatory clearance for the underlying platform and algorithm.

## **Otsuka Agreement**

The agreement between Otsuka and Medibio has progressed through several phases, 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.

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

The Company's cash position at 30 June 2018 was A\$6.1 million. During the quarter, the Company had \$0.1 million inflows and \$5.6 million outflows of cash. The cash receipts represent payments from customers, grant funding, and interest. Cash expenditures were used for recurring business activities, including the development and commercialisation of products, acquisition and integration of the Vital Conversation business, payment of FDA clinical trial expenses, and one-time payments associated with the termination of certain employees. The Company anticipates additional cash inflows from customer payments, Australian R&D tax grant, and payments from partly paid shareholders. Anticipated cash available for use by the Company is A\$9.5 million.

During fiscal year 2019, we expect a decrease in net quarterly cash outlays resulting from the conclusion of our FDA clinical trial, inflows from customers on product sales, and cost savings following certain cost reduction measures taken by the Company, including closure of its Melbourne office and reductions in staffing. Our focus will continue to be on product development, scientific research, regulatory filings, and marketing activities associated with advancing our technology in commercialisation.

## **Closing**

This quarter continues a transformational year during which Medibio has significantly expanded our patent portfolio, built a world-class technology, data science and medicine team, completed an acquisition, received ISO 13485, CE Mark, and TGA approval, written peer reviewed scientific publications, created a robust pipeline of products, and filed our FDA De Novo submission. With commitment to exceptional product quality and operational excellence, we work towards transforming mental health care delivery. Objectively!!

Warmest Regards and Be Well,

A handwritten signature in blue ink, appearing to read 'JG Cosentino', with a large, sweeping flourish at the end.

Jack G. Cosentino  
Managing Director & CEO

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

- Submitted FDA De Novo Application
- Published Scientific Paper
- Received TGA approval
- Appointed a new Company Secretary
- Signed Corporate Health Customer Contracts
- Received CE Mark Certification
- Launched Corporate Health Product
- Assembled the Scientific Advisory Board
- Acquired Vital Conversations



Medibio will be providing an audio webcast presentation on the quarterly cashflow results scheduled for 11:00am AEST on 1st August 2018 with the below details.

Australia: +61 2 8355 1054

United States: +1 914 614-3426

Access Code: 613 373 995

Registration URL: <https://attendee.gotowebinar.com/register/5257513152268620033>

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.

#### **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 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 Enquiries:</b> Josh Purdy Senior Public Relations Manager Medibio Limited <a href="mailto:josh.purdy@medibio.com.au">josh.purdy@medibio.com.au</a> T: +1 952 314 1216	<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")**

30 June 2018

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (...12...months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	47	113
1.2 Payments for		
(a) research and development	(1,807)	(6,164)
(b) product manufacturing and operating costs	(5)	(5)
(c) advertising and marketing	(511)	(1,189)
(d) leased assets	-	-
(e) staff costs	(1,805)	(5,119)
(f) administration and corporate costs	(1,002)	(3,621)
1.3 Dividends received (see note 3)		
1.4 Interest received	60	86
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	28	3,295
1.8 Other (GST refund)		222
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(4,995)</b>	<b>(12,382)</b>



Consolidated statement of cash flows	Current quarter \$A'000	Year to date (...12...months) \$A'000
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) property, plant and equipment	-	-
(b) businesses (see item 10)	(400)	(400)
(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	-	-
2.5 Other (leasehold security deposits, net)	(85)	(85)
<b>2.6 Net cash from / (used in) investing activities</b>	<b>(485)</b>	<b>(259)</b>
<b>3. 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	-	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 Net cash from / (used in) financing activities</b>	<b>-</b>	<b>13,787</b>

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (...12...months) \$A'000</b>
<b>4. 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	11,594	5,010
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(4,995)	(12,382)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(485)	(259)
4.4 Net cash from / (used in) financing activities (item 3.10 above)		13,787
4.5 Effect of movement in exchange rates on cash held	10	(32)
<b>4.6 Cash and cash equivalents at end of quarter</b>	<b>6,124</b>	<b>6,124</b>

<b>5. 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	367	198
5.2 Call deposits	5,757	11,396
5.3 Bank overdrafts	-	-
5.4 Other (provide details)	-	-
<b>5.5 Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>6,124</b>	<b>11,594</b>

**6. Payments to directors of the entity and their associates**

	<b>Current quarter \$A'000</b>
6.1 Aggregate amount of payments to these parties included in item 1.2	121
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 director and director related entity's for the June 2018 quarter.	

<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.		

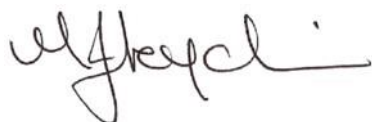
<b>9. Estimated cash outflows for next quarter</b>	<b>\$A'000</b>
9.1 Research and development	(875)
9.2 Product manufacturing and operating costs	(25)
9.3 Advertising and marketing	(250)
9.4 Leased assets	-
9.5 Staff costs	(2,150)
9.6 Administration and corporate costs	(1,375)
9.7 Other	-
<b>9.8 Total estimated cash outflows</b>	<b>(4,675)</b>

10. Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	Acquisitions	Disposals
10.1 Name of entity	Vital Conversations Pty Ltd	
10.2 Place of incorporation or registration	Subiaco, WA	
10.3 Consideration for acquisition or disposal	\$492,230 (\$400,000 in cash, \$92,230 in MEB shares)	
10.4 Total net assets	\$492,230*	
10.5 Nature of business	Psychological health services	

**Additional Information**

\*Fair value of net assets acquired are currently calculated under provisional accounting.

- 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: 31 July 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.