Quarterly ASX Update

Medibio Limited (ASX:MEB)

31 January 2017

Highlights

- US healthcare firm, LifeQ, and Medibio partner to deliver scalable mental wellness diagnostics.
- Key milestones in the validation of technology for the diagnosis of depression
  - Excellent performance in the pilot phase of its US Validation Study ***– 81% diagnostic accuracy and 82% sensitivity*** for delineating individuals with Major Depressive Disorder
  - University of Ottawa Study demonstrated improved classification ***accuracy of 86%*** in diagnosing Major Depressive Disorder (MDD) based on 889 patients
- Entered binding integration and value-added reseller agreement with Medtronic.
- Partnered with HBF Insurance and Vital Conversations on Australia's biggest mental health check-in.

Corporate

- $13.5 million raised via the placement of 33,750,000 ordinary shares at $0.40/share
- All shareholder resolutions were passed at the Annual General Meeting on 29 November 2016.
- The Company's cash position at 31 December 2016 was $12.8 million after normalized quarterly expenses of $1.32 million.

LifeQ and Medibio look to partner to deliver scalable mental wellness diagnostic

Medibio and LifeQ based in Alpharetta, Galverston USA, executed a non-binding Memorandum of Understanding (MOU) in December as the first step to a partnership agreement. Together, Medibio and LifeQ aim to deliver mental wellness diagnostic and management solutions to a wide range of users through insurance and corporate programs.

The MOU proposes a revenue sharing arrangement where Medibio receives 70% of revenue from Medibio diagnostics collected and distributed via the LifeQ platform and 80% of revenues via the Medibio platform.

LifeQ comprises a uniquely multi-disciplinary team led by computational systems biologists. Its platform, to track an individual's physiology continuously, requires inputs from wrist-based wearables. LifeQ uses bio-mathematical models to translate these inputs into information with the potential to improve human health. LifeQ uses real time and predictive data to create digital simulations of human physiology. The power of its platform is providing users with a single source of information helping them understand every aspect of their health.

The partnership combines LifeQ's unique suite of information streams from wrist-based wearables and its systems biology modelling with Medibio's 15 years of mental health research and objective test for mental wellness.

Under the MOU, Medibio shall integrate its solutions and with the LifeQ Platform that connects an ecosystem of domain experts, all of whom will now be able to access and use these information outputs. LifeQ technology is empowering people to redefine the way they engage with their unique individual human biology. By leveraging LifeQ's systems biology based approached enabling the extraction of a range of accurate measures and metrics from wrist based wearables, Medibio's solution will be extended through continuous measurement and made available at scale.

Validation of Depression Diagnostic

During the quarter, the Company achieved two key milestones in the validation of its technology for depression diagnosis. (Depression is estimated to afflict 350 million people worldwide.) These comprised first set of results from the validation study with Johns Hopkins University and the main phase of the University of Ottawa study.

Johns Hopkins Study – Pilot Stage Results (81% Accuracy)

On 21 December, Medibio announced preliminary results from the pilot phase of its first study of its Depression Diagnostic. The principal investigators were Dr. Naresh Punjabi (Professor, Johns Hopkins Medicine) and Dr. Francis Mondimore (Director, Mood Disorders Clinic Johns Hopkins Medicine).

Subjects underwent heart rate monitoring using a Holter (ECG) monitor for a period encompassing one day's sleep cycle. The subjects were classified as depressed or non-depressed by two independent psychiatrists, each performing M.I.N.I. [(2)] examination. Agreement between the two psychiatrists and sufficient ECG data quality were the includion criteria. The results are based on full datasets from 26 subjects (11 with MDD, 15 healthy controls) which were included in the pilot phase.

Medibio's technology achieved diagnostic accuracy of 81% and sensitivity of 82% for delineating individuals with Major Depressive Disorder (MDD) from non-depressed individuals. This significantly outperforms the existing standard-of-care diagnosis in the US primary care setting (33-50% accuracy) and among psychiatrists (70% concordance).

The study is the first **prospective** validation for depression done with a leading US university and is intended to support FDA clearance of Medibio's depression algorithm. Further, the data provided confidence of the clinical performance expected in the US primary care setting. Of the 15 healthy controls, two had a prior history of depression, one had substance abuse issues and one was on medication for ADHD. Seven of the MDD subjects were on medication for depression (with 5 of these on multiple medications) and several particpants (both normal controls and MDD) with diabetic comorbidity.

University of Ottawa – Main Stage Results (86% Accuracy)

On November 2, Medibio announced successful completion of Stage 2 of its University of Ottawa retrospective study, with diagnostic accuracy increasing to 86% for distinguishing individuals with MDD from non-depressed individuals (previously 83%). The classification algorithm leverages objective biomarkers computed from overnight heart rate recordings and sleep annotations to distinguish between the clinical groups. The clinical assessments of psychiatric status were conducted by two independent clinicians.

An additional 563 patients (272 with MDD and 291 controls) were processed in the validation study, increasing the study sample size by 300%. The study now includes 889 patients, with 630 (315 MDD & 315 controls) having been used for additional algorithm training and 259 (125 MDD & 134 controls) used for blind assessment. This validation was a significant milestone in the Company's development of a proprietary objective test for the diagnosis of depression as it was based on a highly significant sample size of almost 900 patients. Importantly, the cohort size is between 5-10 times required in our clinical studies to support FDA clearance and European Medical Devices Directorate (EMDD) approval for a CE Mark.

The final 300 patients from the University of Ottawa will be used to generate an Independent Validation paper (peer reviewed) to be published by the University of Ottawa. Ongoing work includes further identification of discriminating biomarkers to improve the diagnostic accuracy of the algorithm, incorporation of the new data for further algorithm training and validation of additional algorithms. Following this, Medibio will expand and validate its diagnostic algorithm for depression to identify the different presentations of depression, increasing its clinical utility.

Binding integration and value-added reseller agreement with Medtronic

The Company entered a binding Integration and Value-Added Reseller Agreement with the Health Informatics & Monitoring division of Medtronic. Under the Agreement, Medibio integrated Medtronic's Zephyr BioPatch™ medical products into its Digital Mental Health Platform.

The Agreement provides Medibio non-exclusive rights to purchase and re-sell Medtronic's Zephyr BioPatch™ medical products and accessories as part of its solution. The initial term of the Agreement is 15 months and allows Medibio to resell the Zephyr™ products in the United States of America and in any other countries mutually agreed between the parties in future.

Medtronic and Medibio intend to explore joint opportunities around Medibio's mental health solution with key clients.

Australia's biggest mental health check-in

During the quarter, Medibio signed on as a delivery partner on a mental health campaign led by corporate psychological health services organization, Vital Conversations, in conjunction with not-for-profit health insurer, HBF.

Australia's Biggest Mental Health Check-in campaign aimed to encourage Australians to undertake a mental health check facilitated by Vital Conversations. The program was a combination of Vital Conversations self-report based, subjective diagnostic methodology and Medibio's objective method stress measure.

The response to the check-in was excellent with more than 1500 registrations received and several leading corporates participating in the program. Follow-up on participants has shown that improvements in mental health have been significant. Feedback from participating corporates has been excellent, on the insight the de-identified data provides as a company snapshot and the ability to provide a cost-effective offering for their employees.

Due to the high demand from corporates, Medibio is in discussions with Vital Conversations about running the check-in again in Q2, 2017. Other less tangible but significant benefits for Medibio have been the awareness created for its workplace stress product prior to commercial launch and the acquisition of new (de-identified) data files with corresponding stress assessments. This data significantly increases the size of Medibio's dedicated overnight CHR file database and corresponding stress assessments.

Corporate

$13.5m Capital Raising

During the quarter, the Company raised $13.5 million via the placement of 33,750,000 ordinary shares at $0.40 each. The placement was conducted in two tranches.

The placement was oversubscribed from domestic and foreign institutions with Fidelity International, on behalf of various accounts, entering the register and becoming a major shareholder.
Most the placement proceeds are committed to fast-tracking clinical studies to support FDA and EMDD filings and the associated regulatory work.

Quarterly Expenditure

Total normalized cash expenses during the quarter were approximately $1.32 million (as outlined in Table 1 below) compared with budgeted expenditure of $1.1million. The increase was due to a ramp-up of operations in November and December following the capital raise. Budgeted expenditure next quarter is $1.4 million with the increase due to the continued ramp-up of activities following the capital raise.

Table 1 – Operating cash outflows reconciliation (non-recurring items removed)

Cash outflows from operating activities (Section 1. App 4C)		Figures in App 4C (A$'000)	Correction for non-recurring item	Normalised cash outflows
1.2 Payments for				
(a) Research and development		(1,346)	738 (1,2,3,4)	(608)
(e) Staff Costs		(605)	276 (5,6)	(329)
(f) Administration and Corporate Costs		(1,909)	1,530 (7,8,9,10,11,12)	(379)
Total cash outflows from operating Activities				(1,316)

Non-recurring Items

(1) $240,000 – up-front payment for life of the PTSD collaboration (including clinical research) with Emory University

(2) $133,500 – expenses associated with internal stress study (data collection completed in Q1 2017)

(3) $226,000 - bullet payment upon completion of contract related to stress solution over past 48 months

(4) $138,000 – firmware upgrades and purchase of 1,500 heart rate monitors for stress pilots/internal stress study

(5) $209,000 – non-cash issue shares/options to staff/board as approved at the 2016 AGM

(6) $67,000 – one of cash bonus to US staff member

(7) $111,000 – costs associated with Audit, Printing/mailing of Annual report and AGM

(8) $58,000 – cost associated with now discontinued corporate mandates

(9) $132,000 – interest payment on the US$2.5m convertible Note which was repaid subsequently to the quarter end

(10) $338,000 – expenses associated with the 2016 R&D rebate which were expensed at the time of receipt

(11) $95,000 – short term rent expenses associated with internal stress study (data collection completed in Q1 2017)

(12) $796,000 – non-cash issue shares/options to staff/consultants as approved at the 2016 AGM (including a number of one off sign-on/performance bonus)

General Meeting

Medibio held its Annual General Meeting of Shareholders on 29 November. All resolutions tabled at the meeting passed on a show of hands.

After an exhaustive search during the quarter, the Company looks forward to appointing another Non-Executive Director soon.

Cash

The Company's cash position at 31 December 2016 was $12.8 million.

About Medibio Limited

Medibio (ASX: MEB) is a medical technology company developing a new objective test to assist in the diagnosis of depression and other mental health disorders and chronic stress. This test utilises circadian heart rate variability. The technology is based on measured differences in circadian heart rate and measures of heart rate variability. The technology is based on the scientific finding that circadian heart rate variability is a sensitive measure for depression, other mental health disorders and chronic stress. The technology consists of a heart monitor that sends ECG recordings wirelessly to the internet where a proprietary algorithm analyses and delivers a quantifiable measure which can be used by a clinician to assist in diagnosis. The Technology has the potential to be the first FDA-approved objective, evidence based approach to the diagnosis of depression and other mental health disorders. The technology has already benefited from 10 years of laboratory research and Medibio is undertaking a number of pivotal studies to validate its clinical utility.

Further Information:	
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+Rule 4.7B

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 2016

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (...6....months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(1,346)	(2,217)
	(b) product manufacturing and operating costs		
	(c) advertising and marketing		
	(d) leased assets		
	(e) staff costs	(605)	(835)
	(f) administration and corporate costs	(1,909)	(2,236)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	9	10
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	3,074	3,074
1.8	Other (GST refund)	12	184
1.9	**Net cash from / (used in) operating activities**	**(765)**	**(2,020)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) property, plant and equipment	-	-
	(b) businesses (see item 10)	-	-
	(c) investments	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (...6....months) $A'000
	(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 (see note 3)	-	-
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	14,475	14,475
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	700	786
3.4	Transaction costs related to issues of shares, convertible notes or options	(1,268)	(1,268)
3.5	Proceeds from borrowings	-	170
3.6	Repayment of borrowings	(420)	(420)
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**	**13,487**	**13,743**

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	76	1,075
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(765)	(2,020)
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)	13,487	13,743

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (...6....months) $A'000**
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	**Cash and cash equivalents at end of quarter**	**12,798**	**12,798**

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	35	48
5.2	Call deposits	12,763	28
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)**	**12,798**	**76**

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	195
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

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

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)	-	-

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.

Loan of $170k was provided mid Sept 2016 to provide additional funds until the receipt of the $3,074k R&D Rebate in early Oct 2016.

The Loan was repaid in October 2016 after the receipt of the R&D Rebate.

9.	**Estimated cash outflows for next quarter**	**$A'000**
9.1	Research and development	675
9.2	Product manufacturing and operating costs	-
9.3	Advertising and marketing	25
9.4	Leased assets	-
9.5	Staff costs	450
9.6	Administration and corporate costs	250
9.7	Other (provide details if material)	-
9.8	**Total estimated cash outflows**	**1,400**

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: ..... Date: .....31 January 2017.....
(~~Director~~/Company secretary)

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.