

ASX Market Update

Medibio Limited (ASX:MEB)



31 July 2016

Medibio Limited (ASX: MEB) (“Medibio” or “the Company”) is pleased to report on its activities for the June 2016 quarter.

Highlights

- First commercial pilot study validated the Company’s Stress Product, achieving 86% agreement with psychological measures – successful identification of “at-risk” cases not picked up by conventional psychological screening
- Medibio in discussions with Vital Conversations regarding a larger workplace rollout following the successful pilot
- Completed development and validation of a new sleep staging algorithm with outstanding results achieved - using ECG data only, Medibio was able to accurately distinguish between the five stages of sleep with diagnostic accuracies of 86-95%
- Sleep testing market of US\$4B represents a second stand-alone opportunity for Medibio.
- Sleep test results represents powerful early demonstration of Medibio’s technology coupled with the world’s largest database of overnight ECG data and corresponding mental health assessment.

Corporate

- Total cash available to the company of approximately \$6 million over the next 14 months
- Cash position as at June 30th 2016: \$1.1m
- Company anticipates receiving approximately \$2.8m R&D rebate for the year ending June 30 2016 in the current quarter
- Forward budgeting indicates that the company will receive a \$2.1-2.5m R&D cash rebate for the year ending 30 June 2017 with this rebate expected to be received in approximately 14 months.
- Increase in R&D expense during the quarter a one off due to advance payments to qualify for the current year R&D rebate.

First commercial pilot study completed with Vital Conversations

During the quarter Medibio successfully completed the first commercial pilot study of its workplace stress product. The pilot study was undertaken with corporate wellness partner, Vital Conversations (Vital), on behalf of a corporate client with more than 5,000 employees in Australia.

Vital is in active discussions with the client about a larger roll out, as well as a new client considering a similar corporate pilot.

The Company conducted the five-week pilot study of 66 employees using a three category stress ratings system of mild (low-risk), moderate, and severe (at-risk). In conjunction with the Medibio Workplace Stress assessment, Vital also undertook traditional psychological workplace assessment that included self-report questionnaires screening for depression, anxiety and stress, sleep quality, resilience and coping styles. This allowed Medibio's objective stress assessment to be compared with conventional psychiatric measures.

The 'normal' to 'mild' scan results comprised approximately 63% of the pilot population. These results demonstrated an 86% agreement with traditional self-report stress measures at this low risk end of the wellness continuum, where self-report bias is not generally an issue.

At the high risk end, this pilot successfully demonstrated one of the core competencies of Medibio's objective Workplace Stress Test. That is, the ability to identify "at-risk" employees where the traditional subjective measures often fail due to self-report bias.

A number of participants were accurately identified to be in the severe, or "at-risk" category, which was on one occasion in conflict with their self-report. During a follow up interview with Vital, which was required for all severe stress results under the pilot study protocol, a participant, who received a severe result but was categorised as normal by the conventional self-report screening, disclosed they had under self-reported their symptoms. They were able to gain psychological support for a longstanding serious stress-related problem and the Medibio Stress Test allowed for participants identified in the severe category to be appropriately treated for a mental health issues while continuing their work roles.

Medibio is currently completing two additional pilot studies of its workplace stress product, one with a major Australian corporation with more than 10,000 employees and the second with a potential wellness channel partner.

Discussions regarding Medibio's Workplace Stress product are actively proceeding with a number of US organisations following Medibio's participation in the ATA (American Telemedicine Association) Trade show in Minneapolis from May 14-17. The excellent results from this pilot will greatly assist in advancing these discussions.

***Self-Report Bias**

It has been widely recognised in the literature that self-report bias often threatens the validity of psychological research conducted in business settings, and thus hinders the development of theories of organisational behavior. Self-report bias, or the tendency to under-report mental health symptoms in the more serious range, is recognised as *"particularly likely in organisational behavior research because employees often believe there is at least a remote possibility that their employer could gain access to their responses"*.

Development and Validation of New Sleep Staging Algorithm

Medibio completed development and validation of a new sleep staging algorithm with outstanding results achieved.

Using ECG data only, Medibio was able to accurately distinguish between all stages of sleep with diagnostic accuracies of 86-95%. The best published historical results have been in the 70% range for all stages of sleep.

The project is part of the Company’s collaborative research and development effort with four leading US universities. Under this collaboration, Medibio secured in excess of 120,000 hours of overnight physiological (ECG, EEG and other biometrics) data files to be analysed by the Company’s Digital Mental Health Platform. This allowed Medibio and its research partners to generate proxy-clinical trial outcomes and meta-data analyses from more than 15,000 patients retrospectively. The sleep staging results have been generated and validated using data supplied by the Johns Hopkins University School of Medicine.

Under the project, Medibio used advanced machine learning techniques on a randomly selected set of 55,000 hours of overnight ECG files (with corresponding sleep staging information from Johns Hopkins) to develop an algorithm to use ECG data only to place the individual into one of the five sleep stages. This algorithm was validated using an additional 13,000 hours of randomly selected files. The sleep stages derived from the new ECG algorithm being validated against the sleep staging data from traditional PSG/EEG

5 min interval sleep stage classification

Sleep Stage	Training sample size	Test sample size	Test Accuracy	Test F1-score
0	331,108	141,904	0.86	0.86
1	17,675	7,575	0.95	0.95
2	214,292	91,840	0.90	0.89
3	15,775	6,761	0.95	0.95
4	534	230	0.99	0.99
5	82,831	35,499	0.93	0.93

methods.

The prospect of automatic sleep stage classification with using cardiorespiratory signals has attracted increasing attention in medical research with numerous attempts being made to find a method to accurately sleep score using ECG data. In contrast to the traditional manual scoring based on polysomnography, ECG data can be measured using unobtrusive techniques promising the application for personal and continuous home sleep monitoring.

This is the first in a number of proxy clinical studies and research projects underway using more advanced machine learning techniques and Medibio’s extensive data base. Existing algorithms for mental health will be improved by allowing Medibio to investigate new analytical metrics specific to sleep stages. In addition, the ability to accurately distinguish between sleep stages using only ECG data has significant commercial potential in its own right. The Global Sleep Testing Services Market has been estimated at US\$4.1B increasing to US\$8.1B by 2021.

Medibio is currently in discussions with an international sleep clinic group to further validate Medibio’s sleep staging breakthrough in a prospective study. This prospective study will open the opportunity for the company to commercialise this sleep staging algorithm as a stand-alone business opportunity in the area of home sleep monitoring and sleep clinics.

Medibio is continuing to build a broad base of collaborators to significantly increase its data assets. In combination with its advanced machine learning analytics cloud solution, this will allow the Company to extract new insights regarding the link between mental health and circadian heart-rate architecture.

Corporate

Cash

The Company's cash position at June 30th 2016: \$1.1 with R&D rebates of \$1.7m received for the year ending June 30th 2015. The Company anticipates receiving a \$2.8m R&D rebate for the year ending June 30 2016. With a large portion of this rebate to be received during the current quarter. Forward budgeting indicates that the company will receive a \$2.1-2.5m R&D cash rebate for the year ending 30 June 2017 with this rebate expected to be received in approximately 14 months.

This brings total cash available to the Company over the next 14 months to approximately \$6-6.4 million sufficient to fund all current activities in the year ahead.

The was an approximate \$0.5m increase in R&D expense during the quarter. This is a one off associated with advance payments to qualify R&D activities for the current year R&D rebate.

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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Appendix 4C

Quarterly report for entities admitted on the basis of commitments

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

Name of entity

Medibio Limited

ABN

58 008 130 336

Quarter ended ("current quarter")

30 June 2016

Consolidated statement of cash flows

Cash flows related to operating activities	Current quarter \$A'000	Year to date (...12.... months) \$A'000
1.1 Receipts from customers	-	20
1.2 Payments for		
(a) staff costs	(242)	(746)
(b) advertising and marketing	-	-
(c) research and development	(779)	(1,799)
(d) leased assets	-	-
(e) other working capital	(450)	(1,846)
1.3 Dividends received	-	-
1.4 Interest and other items of a similar nature received	5	23
1.5 Interest and other costs of finance paid	(166)	(359)
1.6 Income taxes paid	-	-
1.7 Other (R&D Rebate)	526	1,742
1.7 Other (GST refunds)	60	194
Net operating cash flows	(1,046)	(2,771)

+ See chapter 19 for defined terms.

Appendix 4C
Quarterly report for entities
admitted on the basis of commitments

	Current quarter \$A'000	Year to date (..12..... months) \$A'000
1.8 Net operating cash flows (carried forward)	(1,046)	(2,771)
Cash flows related to investing activities		
1.9 Payment for acquisition of:	-	-
(a) businesses (item 5)	-	-
(b) equity investments	-	-
(c) intellectual property	-	-
(d) physical non-current assets	-	-
(e) other non-current assets	-	-
1.10 Proceeds from disposal of:	-	-
(a) businesses (item 5)	-	-
(b) equity investments	-	-
(c) intellectual property	-	-
(d) physical non-current assets	-	-
(e) other non-current assets	-	-
1.11 Loans to other entities	-	-
1.12 Loans repaid by other entities	-	-
1.13 Other	-	-
	-	-
Net investing cash flows		
1.14 Total operating and investing cash flows	(1,046)	(2,771)
Cash flows related to financing activities		
1.15 Proceeds from issues of shares, options, etc.	50	3,142
1.16 Proceeds from sale of forfeited shares	-	-
1.17 Proceeds from borrowings	-	-
1.18 Repayment of borrowings	-	-
1.19 Dividends paid	-	-
1.20 Other (less Equity raising costs)	-	(244)
	50	2,898
Net financing cash flows		
Net increase (decrease) in cash held	(996)	127
1.21 Cash at beginning of quarter/year to date	2,071	948
1.22 Exchange rate adjustments to item 1.20	-	-
1.23 Cash at end of quarter	1,075	1,075

+ See chapter 19 for defined terms.

Payments to directors of the entity and associates of the directors

Payments to related entities of the entity and associates of the related entities

		Current quarter \$A'000
1.24	Aggregate amount of payments to the parties included in item 1.2	72
1.25	Aggregate amount of loans to the parties included in item 1.11	-

1.26 Explanation necessary for an understanding of the transactions

Directors fees for the quarter

Non-cash financing and investing activities

2.1 Details of financing and investing transactions which have had a material effect on consolidated assets and liabilities but did not involve cash flows

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2.2 Details of outlays made by other entities to establish or increase their share in businesses in which the reporting entity has an interest

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Financing facilities available

Add notes as necessary for an understanding of the position.

		Amount available \$A'000	Amount used \$A'000
3.1	Loan facilities	-	-
3.2	Credit standby arrangements	-	-

+ See chapter 19 for defined terms.

Appendix 4C
Quarterly report for entities
admitted on the basis of commitments

Reconciliation of cash

Reconciliation of cash at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts is as follows.	Current quarter \$A'000	Previous quarter \$A'000
4.1 Cash on hand and at bank	63	9
4.2 Deposits at call	1,012	2,062
4.3 Bank overdraft	-	-
4.4 Other (provide details)	-	-
Total: cash at end of quarter (item 1.23)	1,075	2,071

Note – The R&D Tax refund of \$1,216,128 for the 30 June 2015 Tax period was received 12 January 2016 and is not reflected in this report

Acquisitions and disposals of business entities

	Acquisitions (Item 1.9(a))	Disposals (Item 1.10(a))
5.1 Name of entity		
5.2 Place of incorporation or registration		
5.3 Consideration for acquisition or disposal		
5.4 Total net assets		
5.5 Nature of business		

Compliance statement

- 1 This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.
- 2 This statement does give a true and fair view of the matters disclosed.



Sign here: Date: 29 July 2016
 (Company secretary)

Print name: Robert Lees

+ See chapter 19 for defined terms.

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 wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.
2. The definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report except for any additional disclosure requirements requested by AASB 107 that are not already itemised in this report.
3. **Accounting Standards.** ASX will accept, for example, the use of International Financial Reporting Standards for foreign entities. If the standards used do not address a topic, the Australian standard on that topic (if any) must be complied with.

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