ASX Market Update

Medibio Limited (ASX: MEB)

INNOVATION IN MIND

30 April 2016

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

Highlights

- Successful pre-submission meeting with the US United States Food and Drug Administration (FDA)
- Swinburne Software Labs partnership - trial success with Apple Watch® and FITBIT® for Medibio's Stress app
- First commercial pilot commenced with Wellness Channel Partner Vital Conversations
- Four leading US universities provided 10,000 physiological data files to Medibio to undertake joint research and development into various mental health conditions
- Highly distinguished US medical expert and Eli Lilly Director joins Medibio Board
- Acquired key patents covering the use of 24-hour heart rate data and circadian heart rate (CHR) technology for the diagnosis of psychiatric conditions subsequent to the end of the quarter

Corporate

- Cash position as at March 31st 2016: $2.07m with an additional $531,000 to be received in the April-June quarter. ($421,000 from the overseas component of the R&D rebate received and an additional $110,000 pending.)
- Company anticipates receiving approximately $2.4m R&D rebate for the year ending June 30 2016.
- Total cash available to the Company of approximately $5 million over the next 12 months.

Successful pre-submission meeting with the US FDA

The Company had a positive pre-submission meeting on its proposed diagnostic for depression. It confirmed the proposed regulatory pathway of Medibio's depression test. Additionally, the FDA confirmed the Company's proposed indications for use, clinical study protocols and data requirements.

At the meeting, the FDA confirmed (based on the information provided in Medibio's pre-submission dossier):

- The Medibio Depression Algorithm is eligible for the de novo [(1)] regulatory pathway
- The FDA expressed no significant concerns with the proposed indications for use
- Medibio's proposed Level of Concern [(2)] for its Depression Algorithm is acceptable to the FDA.

Medibio was pleased with the high level of engagement from the FDA and the collaborative nature of the meeting. The confirmation of the regulatory pathway is an important milestone for the Company.

(1) *de novo Pathway - The de novo pathway was designed for innovative medical devices (ie, those without predicate devices) where controls provide a reasonable assurance of safety and effectiveness. The de novo process leads to a Class I, or in Medibio's case, a Class II classification. It has a 120-day review cycle compared with a 90-day review period for a 510(k).*

(2) *Level of* Concern - the FDA recommends submissions state the Level of Concern determined for a Software Device. The Level of Concern is based on how the operation of the software associated with device function affects the patient or operator. The extent of the documentation required in an FDA a pre-market submission depends on the device's Level of Concern.

Swinburne Software Labs partnership - trial success with Apple Watch® and FITBIT® for Medibio's Stress app

During the quarter, Medibio partnered with Swinburne Software Innovation Lab (SSIL) to evaluate the market-leading wrist-based wearable devices as an alternative to ECG monitors in Medibio's Corporate Stress Product.

SSIL confirmed the *Apple Watch* and *Fitbit Surge* met all performance requirements, with both devices' heart rate data providing a high level of accuracy for Medibio's stress diagnostics and analytics. In addition to validating the quality of data generated by the *Apple Watch* and *Fitbit Surge*, SSIL successfully:

- Completed the work required to collect the data seamlessly from the *Apple Watch* and *Fitbit Surge* in Medibio's cloud-based Digital Mental Health Platform (DMHP);
- Assisted in the calibration of Medibio's stress algorithm to utilise optical pulse rate data, from wearables in addition to ECG data, for stress analysis;
- Benchmarked the heart-rate data quality of the *Apple Watch* and *Fitbit Surge* against a leading medical-grade ECG monitor; and, consequently,
- Significantly expanded market opportunity for Medibio's stress analytics in the corporate and consumer space.

The trial's success with SSIL paves the way for Medibio to integrate these wearables into its Corporate Stress offering. This will capitalize on the growing trend of wearables being offered to employees as part of the Corporate Wellness package. It also opens the way for the release of a Consumer Stress App.

First commercial pilot study with wellness channel partner Vital Conversations

Medibio's first commercial pilot study commenced with corporate wellness partner, Vital Conversations, during the quarter with approximately 50 employees of one of its clients undertaking a stress assessment with Medibio's Corporate Stress Product.

As well as objectively measuring the impact of stress on the participants, the pilot study aimed to measure: usability; employee acceptance and satisfaction; the delivery of Medibio's corporate stress product in a workplace setting; and ability to scale. The study will allow the product to be fine-tuned for commercial launch.

Initial feedback from the participants in the pilot study and Vital Conversations has been very positive. Vital and Medibio are reviewing the pilot results prior to presenting them to the client.

Vitals' client for the commercial pilot is a leading international professional services company with more than 5,000 employees in Australia. Vital noted it had received strong interest for similar programs from other potential corporate clients. Additional updates will be made in due course.

10,000 new physiological data sets provided by leading US and North American institutions

Four leading US and North American universities provided Medibio with 10,000 new physiological data sets to

undertake joint research and development into various mental health conditions. The data sets dramatically

increase Medibio's research and development capabilities and will expand potential commercial offerings for its proprietary Digital Mental Health Platform (DMHP).

From this repository of clinical and physiological data Medibio can generate proxy-clinical trial outcomes and meta-data analyses from more than 15,000 patients retrospectively. The significant increase in the volume of available data will also allow the Company to refine advanced machine learning techniques to accelerate the optimisation of Medibio's algorithms at the core of its DMHP. The ability to utilise independently acquired data and corresponding psychiatric diagnoses will also add credibility to the Company's findings and its technology within themedical community.

Johns Hopkins School of Medicine, Emory University, Washington University and The Royal's Institute of Mental Health Research, affiliated with the University of Ottawa, supplied the bulk of the new data.

US medical expert and Eli Lilly Director joins Medibio Board

During the quarter Dr Franklyn G Prendergast, MD, PhD was appointed to the Medibio Board of Directors. Dr Prendergast has a long and distinguished career in the US Healthcare industry and his reputation and experience within US healthcare brings tremendous credibility to the company's technology and strategy.

Dr. Prendergast has been a member of the Eli Lilly Company Board of Directors since 1995 and he served extensively for the National Institutes of Health (NIH) on numerous study section review groups and committees. Dr Prendergast is the former Chair of the Department of Biochemistry and Molecular Biology and the former Director for Research at Mayo Clinic from 1989-1992. From 1989-1996, he was a member of the Board of Governors for Mayo Clinic. From 1999-2007, he was member of Mayo Clinic's Executive Committee, the senior most internal governance committee for the entire Mayo system. He served on Mayo Clinic's Board of Trustees continuously between 1992-2009. Dr. Prendergast retired from Mayo Clinic in December of 2014.

On his appointment Dr Prendergast said: ***"I have been keenly watching Medibio's progress and I feel now is the right time to increase my involvement with the company. The future of Mental Health care lies in the increased precision of assessment and timely effectiveness of treatments. The Medibio Digital Mental Health Platform will be needed to realise this vision."***

Key patents acquired covering the diagnosis of psychiatric conditions using CHR

Subsequent to the end of the quarter Medibio acquired (from Heartlink Limited) the Australian, New Zealand and Israeli patents it held under exclusive license on the 'method for diagnosing psychiatric disorders'. The method covers the use of 24-hour heart rate data and circadian heart rate (CHR) technology for the diagnosis of psychiatric conditions and the determination of the effectiveness of treatment.

The acquisition is in line with Medibio's intellectual property (IP) strategy of creating and protecting a dominant, defensible position in the use of CHR technology in the areas of stress and mental health.

The table below summarises Medibio's current patent coverage.

Country	Patent	Status	Title
Australia	720226	Granted	Method for diagnosing psychiatric disorders
Israel	132186	Granted	Method for diagnosing psychiatric disorders
New Zealand	337833	Granted	Method for diagnosing psychiatric disorders by analysis of heart
USA	624502	Granted	Method for diagnosing psychiatric disorders
Canada	228553	Granted	Method for diagnosing psychiatric disorders
USA	pending	Application	Method and System for Monitoring Stress Conditions
USA	pending	Application	Method and System for assessing Mental State

Corporate

Shares issued for patent acquisition

Subsequent to the end of the quarter Medibio issued 4,000,000 fully paid ordinary shares at 30 cents (escrowed for 12 months) as full consideration for the Heartlink Limited patents acquisition noted above.

Cash

The company's cash position as at March 31st 2016 was $2.07m with an additional $531,000 to be received in the April-June quarter. Of this, $421,000 from the overseas component of the R&D rebate has been received with the $110,000 balance expected shortly. Additionally, the Company anticipates receiving a $2.4m R&D rebate for the year ending June 30 2016. This brings total cash available to the Company to approximately $5 million over the next 12 months, sufficient to fund all current activities in the year ahead.

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 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")

31 March 2016

Consolidated statement of cash flows

		Current quarter $A'000	Year to date (...9....months) $A'000
Cash flows related to operating activities			
1.1	Receipts from customers	-	20
1.2	Payments for (a) staff costs	(252)	(504)
	(b) advertising and marketing	-	-
	(c) research and development	(331)	(1,020)
	(d) leased assets	-	-
	(e) other working capital	(499)	(1,396)
1.3	Dividends received	-	-
1.4	Interest and other items of a similar nature received	8	18
1.5	Interest and other costs of finance paid	-	(193)
1.6	Income taxes paid	-	-
1.7	Other (R&D Rebate)	1,216	1,216
1.7	Other (GST refunds)	36	134
	Net operating cash flows	178	(1,725)

+ 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 (..9.....months) $A'000
1.8	Net operating cash flows (carried forward)	**178**	**(1,725)**
	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**	178	(1,725)
	Cash flows related to financing activities		
1.15	Proceeds from issues of shares, options, etc.	-	3,092
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)
	Net financing cash flows	-	2,848
	Net increase (decrease) in cash held	178	1,123
1.21	Cash at beginning of quarter/year to date	1,893	948
1.22	Exchange rate adjustments to item 1.20	-	-
1.23	**Cash at end of quarter**	2,071	2,071

+ 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	70
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

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

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.

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	9	54
4.2	Deposits at call	2,062	1,839
4.3	Bank overdraft	-	-
4.4	Other (provide details)	-	-
	Total: cash at end of quarter (item 1.23)	2,071	1,893

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 April 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.

+ See chapter 19 for defined terms.