

Quarterly ASX Update and Cashflows

Medibio Limited (ASX:MEB)

27 April 2017

Quarterly Update and Message from new CEO of Medibio Limited

Sydney, Australia – 27 April 2017: - Medibio Limited (ASX: MEB), a medical technology company that has developed an objective test to assist in the diagnosis of depression, chronic stress and other mental health disorders, provides the following quarterly update and message to shareholders from Jack G. Cosentino, CEO & Managing Director of Medibio Limited:

It is with tremendous privilege and honour that I present this update as the first of many performance and metric updates on the progress of Medibio Limited. The intent of these updates is to clearly outline goals, progress and strategy as Medibio becomes the leader in objective clinical decision tools for mental health. We at Medbio are committed to clear, transparent, and direct messaging to investors, supporters, vendors, partners and employees on this exciting journey. We promise to achieve key milestones that will advance this company. Since joining the organization on Feb 16th, 2017, we have built upon the world-class team and developed a new plan that will deliver a leadership position in mental health and create a clear and attainable roadmap for the future. We will maintain a focused approach for all activities and eliminate distractions that could burn funding and time.

Upon joining this company, I immediately commenced evaluation and risk analysis assessment of the entire operation in order to implement a program that supported the rapid growth and scale needed to become dominant in the industry. After identifying essential structural deficits we have strengthened the business systems and processes to ensure we are operating at a level of best industry practice, including resolution of operational matters and strategic alignment with the Board of Directors.

We will be scheduling regular investor calls to provide positive news and updates on our successes and our challenges faced and overcome.

Systems Building

The key of many growth companies is the ability to develop systems and processes to help fuel and sustain growth. We have made significant changes within the operation that allow transparency and visibility for disciplined decision making. The addition of experienced health-tech operators is bringing a mature culture of evidence-based research and process-driven development to the organisation. We are conducting daily process meetings and operational communication to tie our objectives with completed deliverables.

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We have instituted metric tracking per department to ensure good communication and progress toward results.

Quality Systems

Quality systems are critical in a medical technology company and must be sufficient to meet regulatory requirements and produce strong operational performance in the commercialization phase.

We have adopted an official Quality Manual and related standard operating procedures in accordance with ISO 13485 standards and intended to be FDA QSR Compliant. We are actively working with a notified body for expediting a custom designed process to move the company forward in a managed system. Our software is being developed in full conformance with IEC 62304 standards to ensure we have compliant software development processes that meet requirements of design, development, verification and validation.

Human Resources

Our employees are our greatest asset and we have assembled top industry talent and will continue to attract talent globally. Employees are investing their time and energies into delivering a transformative technology to the market.

We are building out our US presence with the opening of two offices in the US. One office is located in the heart of Medical Alley in Minneapolis, MN and will serve as US headquarters where myself and the CFO will be located. We will capitalize on the advantages provided by the large ecosystem of potential Payers, Providers and Medical Device partners. We will expand relationships with top industry brands like Mayo Clinic, Medtronic, UnitedHealth care and others.

We also opened an office in Silicon Valley, CA. This office is focused on the technology and houses a team that gives us a clear market advantage by leveraging tech partners and will continue to collaborate with the technology ecosystem offered there.

Regulatory and Clinical Studies Update

EU Regulatory Pathway

We are actively engaged with our Notified Body, DQS Medizinprodukte GmbH, to achieve CE mark for the Medibio platform and depression diagnostic aid, as well as ISO 13485 certification. We are on track for a technical file submission and quality systems audit later this year. The technical file submission will leverage performance data from research involving the existing dataset obtained through our collaboration with the University of Ottawa.

US Regulatory Pathway

The Depression Diagnostic exploratory and confirmatory studies, covered below, feed directly into the FDA 510(k) *de novo* approval pathway for depression diagnostic aid. Submission to FDA, upon completion of the confirmatory study, is anticipated in late Q1/early Q2 2018.

Depression Diagnostic Exploratory and Confirmatory Studies

Data collection for the exploratory (n=60) study is largely complete, with most of the data having been reviewed for quality and preliminarily analysed. We will use the results from this study, in consultation with FDA, to inform the final sample size of the confirmatory study. Furthermore, Medibio and the investigators at Johns Hopkins University plan to submit the results of the exploratory study to a peer-reviewed journal in Q3 of this year.

Medibio also entered into a research agreement with Deakin University to provide two additional sites for the exploratory study. The two sites are The Melbourne Clinic and the Albert Road Clinic, which have been efficiently enrolling subjects from the large pool of inpatient depressed individuals. The research agreement engages a number of key opinion leaders from leading Australian universities and medical institutions, who can subsequently help provide customer awareness required for commercialization. Moreover, involvement of these sites provides an important source of research subjects, should they be required to keep current timelines around the FDA submission on track.

Treatment response studies soon to launch

In addition to the call for solutions to more precisely diagnose mental health disorders, there is considerable pull from the medical community for an objective means to assess treatment response. As a result, we are initiating a set of exploratory longitudinal studies this year to investigate the monitoring of response to a range of treatment modalities, both pharmacological and stimulation-based.

The first of these studies will be conducted in a grant-funded partnership with Monash University, for which the initiation of enrolment is imminent. Medibio will fund approximately \$30,000 in out-of-pocket expenses, with the balance of the study funded by an Innovation Connections Grant from AusIndustry. This investigator-initiated study involves 135 participants with Major Depressive Disorder, Post-traumatic Stress Disorder, and Obsessive Compulsive Disorder, who are undergoing transcranial magnetic stimulation (TMS). The study will collect overnight ECG, actigraphy data, and rigorous clinical ratings pre-, mid-, post-treatment. As well as developing valuable, independent data on depression treatment monitoring capabilities, the study will also provide insights which may be of use in Medibio's PTSD research partnership with Emory University.

Research and Development

The Silicon Valley research and development organization is headed by Yashar Behzadi, who brings to the company an extensive background in technology development and history in launching first-in-class medical products. Senior team members have also been added and rigorous development processes have been put in place to prepare for regulatory submissions. The team will continue to recruit world-class talent at the intersection of behavioural health, neurophysiology, and data science to add to its already deep capability. The organization has also put in place an aggressive IP strategy to further solidify Medibio's position at the forefront of objective mental healthcare.

Finance

We are very pleased to have recruited a highly credentialed and industry experienced CFO in Mr Brian Mower, who brings to the team a proven background in building the required systems for accounting and in creating of models of scale for reimbursement for the future as we near commercialization.

Quarterly Expenditure and Cash at Bank

The Company's cash position at 31 March 2017 was A\$7.5 million. The company anticipates it will receive a refund of approximately \$3 million from the Australian Taxation Office under the Research and Development Tax Incentive Program for the current financial year plus \$1.3 million from the partly paid shares. Taking available cash over the next 12 months to \$11.8 million.

Total cash expenses during the quarter were approximately \$1.96 million after removing the impact of the early redemption of the US\$2.5 million convertible note and associated final interest payment. This increased expenditure reflected one-off payments of approximately \$250,000 associated with the University of Sydney Study and internal stress study, where data collection has been completed, and the general ramp up of operations as CE Mark and FDA approval are sought simultaneously. Quarterly expenditure is expected to remain at current levels for the next 3 quarters reflecting the costs associated with the completion of the depression confirmatory study and the clinical file preparation and quality systems work associated with the initial CE Mark and FDA submissions for a clinical decision support system for depression.

Corporate Development

One of the initial tasks for Medibio was to evaluate the corporate development potential of the technology. It is clear this business is not lacking opportunity but rather focus in opportunity that will bear fruit long-term as well as some shorter-term wins. We are seeking projects where partners and customers are willing to pay for our technology.

With over 20% of the world's children and adolescents having mental disorders, we entered a fully funded Paediatric mental illness joint venture targeting development of a line of clinical diagnostic tools. This partnership focuses on paediatric depression, anxiety disorder, autism, ADHD, Schizophrenia, and PTSD. This agreement has the potential to fund resources or recognize early revenue by customer validation. About half of mental disorders begin before the age of 14, the ability to accurately detect and treat these illnesses are critical.

We are speaking to some of the largest technology companies in the world about integration on future devices. We are also in discussions with leading pharmaceutical manufacturers, medical device and insurance leaders both in Australia and the US.

Commercial Agreement with Savv-e

Medibio has entered into a commercial agreement with Savv-e which provides Savv-e with exclusive Australian rights ⁽¹⁾ to distribute Medibio's "Unwind" online stress intervention modules. Savv-e is Australia's premier e-learning organisation with a broad mix of top tier industry and government clients including the likes of NAB and Westpac Bank, AMP and QBE Insurance, McDonalds Restaurants, Centrelink and the Department of Defence.

"Unwind" is a seven-module online program specifically formatted for use via tablets and mobile devices that brings together world's best-practice in mind science and digital learning. It helps learners identify, monitor and manage the signs and symptoms of stress. Medibio initially developed "Unwind" to be offered as part of a corporate wellness solution but after an approach by Savv-e the company has agreed to licence it as a stand-alone solution.

The distribution agreement has a 4-year term and is renewable subject to Savv-e meeting various performance targets. Under the agreement Savv-e will be responsible for all marketing, sales, distribution, hosting and associated costs. Medibio will receive a 50% royalty of all sales made by Savv-e.

⁽¹⁾ Exclusive rights are subject to existing Medibio relationships with various insurers/wellness groups

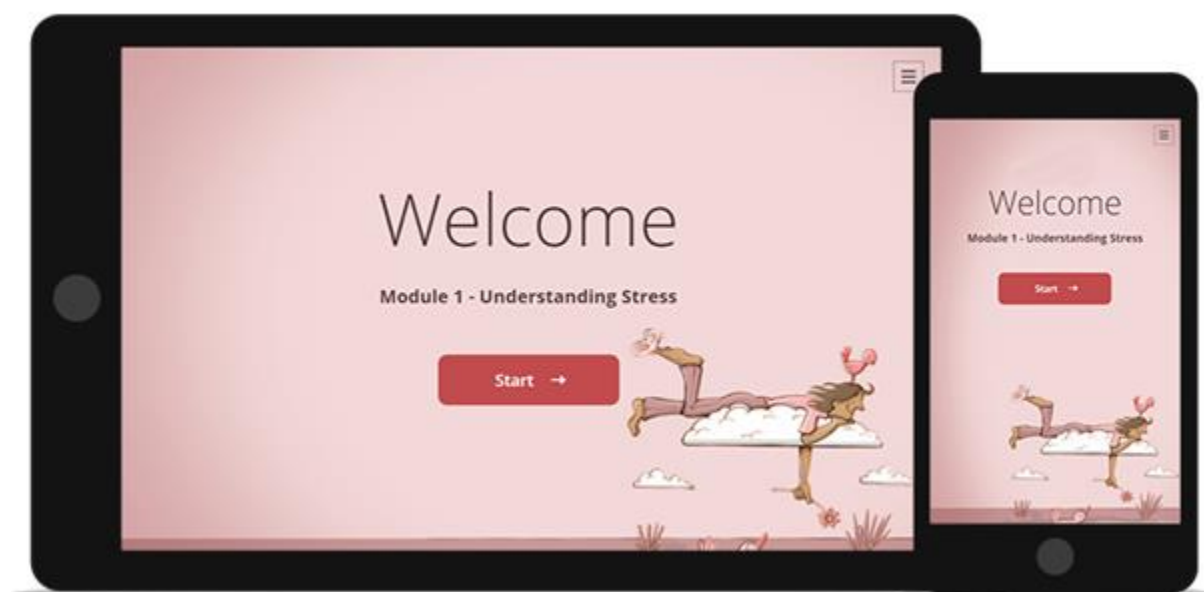


Figure - "Unwind" Module 1 Start Page

Communities of Interest

We have engaged both physician-centric and patient-centric groups to ensure our focus is on providing a dedicated usable solution to the mental health community. This year happens to be the year of Mental Health and Depression for many groups including the World Health Organization. On April 7th, I personally attended the kick-off for the WHO's Health Day and shared the Medibio story at the United Nations. It was clear from the immediate interest from

both thought leaders in industry and governments that we are on the right track to a large underserved population seeking a solution.

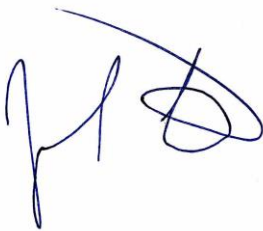
We are here to change the way that the world deals with Mental Health by providing a tool that can be easily accepted as a standard of care for millions around the world in a non-invasive and cost effective way.

Investor Relations

Since arriving in mid-February, I have done two tours of Australia meeting many of our investors personally with one-on-ones. I was very humbled not only for the time to tell my story and thoughts around the company, but also to articulate a new path for the company moving forward. A deep and warm thank you goes out to all who participated in the meetings. It is my true intent to keep the line of communication open and I welcome any and all feedback directly. Whether in person or a phone call, I enjoy the opportunity to speak to new and existing investors in Medibio and assure them that the company is in capable and driven hands, to push this mission forward.

In conclusion, we at Medibio appreciate the over 3,200 plus investors who make Medibio special and we are anxious to share the deliverables as we drive to successful commercialization and operation of the business. With one person dying from mental illness every 40 seconds, we are fortunate to be working with this underserved population that deserves more in their care. By giving clinicians a tool that can help in screening, detecting and diagnosing a detailed picture of a patient's mental health, we work tirelessly to drive this model forward. Thank you.

Warmest Regards,

A handwritten signature in blue ink, appearing to read 'JGC', with a large, sweeping flourish above the letters.

Jack G. Cosentino
Managing Director & CEO

Summary of matters previously announced during the Quarter

- Partnership with Emory University on PTSD (Post Traumatic Stress Disorder)
- CE mark regulatory pathway accelerated and preparation for an ISO13485 certification and technical file submission underway
- US med-tech veteran Jack Cosentino appointed as CEO and Managing Director
- Andrew Maxwell appointed as Non-Executive Director
- Dr Franklyn Prendergast appointed as Chair of Medibio's Advisory
- Newly appointed US based Med-Tech Executive team in place
- Algorithm and data science expert Nathan Kowahl appointed from Intel
- Early repayment of \$3.3 million convertible Note
- Conversion of expiring options into partly paid shares

Further Information:		Website: www.medibio.com.au
Medibio Shareholder Enquiries to: Jack Cosentino CEO and Managing Director Medibio Limited jack.cosentino@medibio.com.au T: + 1 612 314 7201	Medibio Media Enquiries to: Peter Taylor NWR Communications peter@nwrcommunications.com.au T: +61 (0)412 036 231	

About Medibio Limited

Medibio (ASX: MEB), is a medical technology company that has developed an objective test to assist in the diagnosis of depression, chronic stress and other mental health disorders. Based on research conducted over 15 years at the University of Western Australia, this test utilizes patented (and patent pending) circadian heart rate variability and cloud based proprietary algorithms delivering a quantifiable measure to assist in clinical diagnosis. Medibio's depression diagnostic is being validated in clinical studies undertaken by Johns Hopkins University School of Medicine and The University of Ottawa, among others. The clinical trials will support Medibio's application to become the first FDA approved, objective, and evidence based approach to the diagnosis of mental health disorders. Medibio's technology also provides an objective method for the assessment of stress and mental wellbeing that can be translated to the workplace stress/wellbeing market, wearable technology and App market. Located in Melbourne (Vic) Medibio is listed on the Australian Securities Exchange Ltd.

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 2017

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (...9...months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(1,108)	(3,325)
(b) product manufacturing and operating costs		
(c) advertising and marketing		
(d) leased assets		
(e) staff costs	(434)	(1,269)
(f) administration and corporate costs	(456)	(2,692)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	15	25
1.5 Interest and other costs of finance paid	(133)	(133)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	3,074
1.8 Other (GST refund)	19	203
1.9 Net cash from / (used in) operating activities	(2,097)	(4,117)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) property, plant and equipment	-	-
(b) businesses (see item 10)	-	-
(c) investments	-	-

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Consolidated statement of cash flows	Current quarter \$A'000	Year to date (...9...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
3.2 Proceeds from issue of convertible notes	-	-
3.3 Proceeds from exercise of share options	105	786
3.4 Transaction costs related to issues of shares, convertible notes or options	-	(1,268)
3.5 Proceeds from borrowings	-	170
3.6 Repayment of borrowings	(3,298)	(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	(3,193)	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	12,798	1,075
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(2,097)	(4,117)
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)	(3,193)	10,550

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Consolidated statement of cash flows		Current quarter \$A'000	Year to date (...9...months) \$A'000
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	Cash and cash equivalents at end of quarter	7,508	7,508

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	116	35
5.2 Call deposits	7,392	12,763
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)	7,508	12,798

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	106
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 Executive & Non-executive Directors

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	

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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	350
9.7 Other (provide details if material)	-
9.8 Total estimated cash outflows	1,500

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

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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:
(Director/Company secretary)

Date:27 April 2017.....

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.

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