# ASX Announcement

Medibio Limited – 31 July 2019

# Quarterly Update and Message

**Melbourne, Australia and Minneapolis, MN – 31 July 2019: Medibio Limited** (**MEB** or the **Company**)(ASX: MEB)(OTCQB: MDBIF), a health technology company today provides the following quarterly update.

## Key highlights from the quarter

- **Sponsored research agreement with the Department of Biomedical Sciences of Humanitas University**
- **Regulatory and commercialisation strategy update**
- **Medibio algorithm validated in study published in peer review journal**

## Post quarter end event highlights

- **Commercial agreement signed with Compass Group PLC, for two UK-based and one Australia-based pilots for ilumen™**
- **Raised $4,020,000 By Way of a Placement and Fully Underwritten SPP**
- **Announced partnership with digital corporate wellness leader WellteQ**

### Company update

During May, Medibio released an updated investor presentation outlining the Company's re-startup strategy and product pipeline. The presentation can be viewed here.

### Clinical Update

During the quarter, Medibio announced a Sponsored Research Agreement with the Department of Biomedical Sciences of Humanitas University, Milan, Italy. The research agreement supports the Company's continued development of mental health software products based on Medibio's intellectual property. The collaboration extends Medibio's clinical team and reinforces the clinical relevance needed to align with regulatory guidance and market needs. Medibio will maintain all intellectual property generated under this agreement.

Dr Giampaolo Perna, Medibio Scientific Advisory Board member will oversee the collaboration. Dr Perna is currently the Chair of the Department of Clinical Neurosciences at San Benedetto Menni Hospital of the Hermanas Hospitalarias (Como Lake) and Academic Coordinator of Mental Health Area and Adjunct Professor of Humanitas University (Milan), in Italy. Dr Perna earned his degree in Medicine and Surgery at the State University of Milan, followed by a Ph.D. and completed a residency in Psychiatry there as well.

In addition to his role as the Chair of the WPA section on personalised psychiatry, he is also Co-Editor in Chief of the Elsevier Journal "Personalised Medicine in Psychiatry."

For the remainder of the year, Medibio will work closely with the team at Humanitas University whose members have backgrounds in clinical Psychiatry and Psychology. Of note, team members have collectively published 177 peer-reviewed articles focusing on subjects like panic attacks, anxiety disorders and general Psychiatry.

As disclosed to the ASX during June, Medibio received a writ of summons issued in the Supreme Court of Western Australia. The writ relates to a joint venture agreement for research and development of a clinical diagnostic tool that was executed in April 2017 by the Company's previous management. Of note, the writ does not specify the amount of any damages being sought.

The writ claims the Company wrongfully terminated the joint venture agreement and as a result the joint venture partner was unable to perform its obligations under the agreement. To date, the applicant has failed to substantiate that they have performed their obligations under the joint venture agreement. The Company intends to vigorously defend the claims made in the writ.

**Regulatory and Commercialisation Strategy Update**

Medibio announced a new regulatory and commercialisation strategy during the quarter. Effective 29 April, Medibio withdrew the initial De Novo submission filed in July 2018. The decision to withdraw the submission was made after considering input from the FDA, ascertained through the Company's ongoing and positive dialogue with the agency.

The decision was also informed by newly engaged regulatory counsel, the well-known and respected regulatory law firm of DuVal & Associates. The firm, led by proven industry leader Mark DuVal J.D., counsels companies in the medical device, pharmaceutical, biotech and other industries. The firm has specialised expertise doing submission work with the FDA, has worked on many De Novo applications and participated in the first-ever De Novo panel meeting held by the FDA.

With the expertise from DuVal & Associates Medibio identified a revised regulatory strategy which includes filing a new De Novo submission in late CY2019. The Company will not pursue a parallel path through 510(k) submission. The revised strategy follows an extensive evaluation, review and analysis of all FDA regulatory pathways available with these key findings:

- Further analysis on the proposed 510(k) submission revealed limited commercialisation opportunity with the 510(k) due to the limited indications for use that would be obtained.
- Upon extensive review and analysis, these limited indications ultimately did not fit with the Company's strategy. Medibio is better served by building a longer-term FDA strategy for a robust

and sustainable commercial pathway in the U.S., which includes a more attractive indications for use statement only obtainable through the De Novo path.

- Further, the resources required to pursue the parallel paths, De Novo and 510(k), would be prohibitive for the Company, including limiting its ability to respond to increased global interest in the Corporate Health ilumen™ product.

As a result of the Company's decision, resources are now available to aggressively focus on new opportunities in both Australia and the U.S.

With the change in regulatory strategy, the commercialisation strategy has also been refined and updated.

*U.S Regulated Product Commercialisation Opportunities*

The initial commercialisation and licensing opportunities will focus primarily on physician-prescribed inpatient sleep studies.

*ilumen™ Commercialisation*

Medibio continues to advance and consider unsolicited approaches from major global companies. The implementation of opportunities will have regard to the Company's limited resources at this time, while continuing to seek large scale commercialisation of ilumen™. This includes new U.S based opportunities currently in discussion.

Medibio will work to integrate ilumen™ into organisations with global distribution channels. In doing so the Company will seek to generate revenue from annual license fees and royalties based on usage. Medibio will also recoup setup costs for client customisation, when appropriate.

**Scientific Publication Validates Medibio Algorithm**

The Company announced in late June that a clinical research article by Saad et al titled 'Using heart rate profiles during sleep as a biomarker of depression' has been published by *BMC Psychiatry*, an open access, peer-reviewed journal that considers articles on all aspects of the prevention, diagnosis and management of psychiatric disorders.

The article states, "This study demonstrates, for the first time, that changes in heart rate across sleep wake states may be valid physiological markers for the identification of depression in a sample of people with sleep complaints. The heart rate profiling algorithm classified individuals with an accuracy of 79.9%. Specifically, the algorithm was able to detect 82.8% of the depression cases and rule out 77.0% of healthy controls (these results are in line with the preliminary analyses conducted for CE marking). In comparison, the detection rate of depression amongst primary care practitioners is thought to be approximately 47%." (Saad et al., 2019).

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## Quarterly Expenditure and Cash at Bank

The Company continues to make cash conservation efforts on every front, and have found additional ways to reduce costs while maintaining the focus on quality and R&D. Full-time staff positions have been replaced with shorter-term technology vendors, allowing the Company to reduce salary, payroll tax and benefit commitments while hiring specific specialisation skills needed for each phase of R&D. These cost saving measures were recently implemented and will be fully realised in the upcoming quarter. We have negotiated a release from the secondary office lease in the U.S. and sold excess furniture and equipment in both the U.S. and in Australia.

The Company's cash position at 30 June 2019 was A$1.3 million. Cash inflows of approximately $92,000 came from customer payments, interest payments and GST refunds. The Company came in under budget with A$1,613,000 in cash outflows during the quarter, including the initial payment under the R&D contract with Humanitas that will continue into the next fiscal year.

The quarter-over-quarter decrease in cash outflows reflects the Company's continued focus on core activities and the impact of cost reduction strategies discussed above. Included in the cash expenditures were payments on legacy items and costs associated with the departure of former employees. The remaining expenditures were related in part to recurring business activities, including the development of products, FDA-related costs and expenses incurred for regulatory filings. Expenditures also included payments to Mr. David B. Kaysen in his capacity as Chairman, Managing Director and CEO. Ms. Melanie Leydin, Director and Joint Company Secretary, was compensated for corporate secretarial services via payments to Leydin Freyer Corp Pty Ltd. As previously announced the Company is not currently remunerating Non-Executive Directors by way of cash but rather in options as previously approved by shareholders. The Company announced capital fundraising efforts shortly after the financial year end that are expected to provide cash inflows that will last well into calendar year 2020.

## Subsequent Events

In July the Company announced a strongly supported raise of $4,020,000 by way of a placement and fully underwritten Share Purchase Plan ('**SPP**'). Highlights of the announcement include:

- Commitments received for $3.5 million placement at $0.01 per fully paid ordinary share;
- SPP on the same terms, underwritten for $520,000;
- Placement to be completed over two tranches;
- Investors under the placement and Eligible shareholders under the SPP to be offered 1 free attaching option for each new share subscribed for, exercisable at $0.03 until an expiry date of 1 December 2021 and for which the Company will seek quotation on the ASX (subject to meeting ASX listing rule requirements);
- Existing holders of convertible notes have agreed to early conversion of their notes for fully paid ordinary shares at a conversion price equal to the issue price under the Placement. Each noteholder will be offered 1 free option for each Share issued; and
- Issue of securities under Tranche two of the Placement, the SPP (including underwritten shortfall) and the free attaching options upon the conversion of notes are all subject to shareholder approval, to be sought at an EGM to be held on 19 August 2019.

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The Placement was lead managed by CPS Capital Group Pty Limited ('**CPS**'). Under the lead manager mandate, CPS (or its nominees) will be offered to subscribe for up to 90,000,000 options which will be calculated on a pro-rata basis proportionate to the amount of Placement securities issued to investors that are procured by CPS and subject to shareholder approval.

The funds raised by the Company under the Placement will be used for its new De Novo application with the FDA, commercialising its ilumen™ product into different markets, finalising its revised CE mark, and to meeting the costs of the Placement. The additional working capital will enable the continued growth of the Company's current products alongside its future products.

Full details of the raise can be viewed here. Relevant to the raise, the Company has made the following announcements post quarter-end:

- Notice of Extraordinary General Meeting to be held in Melbourne on Monday, 19 August 2019, 11:00AM (AEST)
- Prospectus related to the offer of SPP Shares and Options

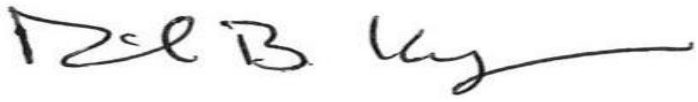
Post quarter-end, Medibio signed commercial agreements with Compass Group PLC ("Compass") to begin two programs of its corporate health product, ilumen™ in the UK. The release on the pilot with the Business and Industry division in the United Kingdom can be viewed here, and the release on the pilot with the Offshore and Remote division in the United Kingdom here. A third agreement for Compass Group Australia to pilot ilumen™ was also announced and full details can be viewed here.

Also post quarter-end, the Company announced a partnership agreement with WellteQ. The parties will work together to implement a unique digital solution incorporating Medibio's mental well-being assessment into Wellteq's personalised and holistic wellness platform. Full details of this announcement can be viewed here.

**Closing**

Thank you for your continued support of Medibio and your time and attention to this report.

Warmest regards,



David B. Kaysen
Chairman, Managing Director and CEO

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– ENDS –

**About Medibio Limited**

Medibio (ASX: MEB) (OTCQB: MDBIF) is a health technology company pioneering the use of objective measures to aid in the early detection and screening of mental health conditions. Through their Corporate Health product, the Company offers mental well-being solutions for businesses and are also developing products to serve the healthcare provider market. The company was founded in Australia, with offices located in Melbourne (Vic) and U.S. offices in 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 and www.asx.com.au.


| **Further Information:** | Website: www.medibio.com.au |
|---|---|
| **Medibio Media Enquiries:**<br>Kristi Hamilton<br>Director, Strategic Communications<br>Medibio Limited<br>kristi.hamilton@medibio.com.au<br>T: +1 952 232 0934 | **Australian Investor Enquiries:**<br>Peter Taylor<br>NWR Communications<br>peter@nwrcommunications.com.au<br>T: +61 (0) 412 036 231 |

*+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 | 30 June 2019 |

| **Consolidated statement of cash flows** | | **Current quarter $A'000** | **Year to date (12 months) $A'000** |
|---|---|---|---|
| **1.** | **Cash flows from operating activities** | | |
| 1.1 | Receipts from customers | 74 | 523 |
| 1.2 | Payments for | | |
| | (a) research and development | (338) | (1,874) |
| | (b) product manufacturing and operating costs | (12) | (36) |
| | (c) advertising and marketing | (12) | (377) |
| | (d) leased assets | - | - |
| | (e) staff costs | (729) | (5,717) |
| | (f) administration and corporate costs | (561) | (3,736) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | 6 | 54 |
| 1.5 | Interest and other costs of finance paid | - | - |
| 1.6 | Income taxes paid | - | - |
| 1.7 | Government grants and tax incentives | - | 3,175 |
| 1.8 | Other (provide details if material) | - | - |
| **1.9** | **Net cash from / (used in) operating activities** | **(1,572)** | **(7,988)** |

| **2.** | **Cash flows from investing activities** | | |
|---|---|---|---|
| 2.1 | Payments to acquire: | | |
| | (a) property, plant and equipment | - | - |
| | (b) businesses (see item 10) | - | - |
| | (c) investments | - | - |
| | (d) intellectual property | - | - |
| | (e) other non-current assets | - | - |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (12 months) $A'000 |
|---|---|---|---|
| 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 | - | 923 |
| 3.2 | Proceeds from issue of convertible notes | - | 2,368 |
| 3.3 | Proceeds from exercise of share options | - | - |
| 3.4 | Transaction costs related to issues of shares, convertible notes or options | (41) | (96) |
| 3.5 | Proceeds from borrowings | - | - |
| 3.6 | Repayment of borrowings | - | - |
| 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** | **(41)** | **3,195** |

| | | | |
|---|---|---|---|
| **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 | 2,932 | 6,123 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (1,572) | (7,988) |
| 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) | (41) | 3,195 |
| 4.5 | Effect of movement in exchange rates on cash held | 14 | 3 |
| **4.6** | **Cash and cash equivalents at end of quarter** | **1,333** | **1,333** |

| 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 | 295 | 881 |
| 5.2 | Call deposits | 1,038 | 2,051 |
| 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)** | **1,333** | **2,932** |

| 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 | 144 |
| 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

Non-Executive Directors are no longer remunerated by means of cash for services effective from 1 January 2019. Payments noted above represent payments to Mr. David B. Kaysen in his capacity as Chairman, CEO and Managing Director. Ms. Melanie Leydin, Director and Joint Company Secretary, was compensated for company secretarial services via payments to Leydin Freyer Corp Pty Ltd.

| 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**<br>*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.

-

| 9. | **Estimated cash outflows for next quarter** | **$A'000** |
|---|---|---|
| 9.1 | Research and development | (440) |
| 9.2 | Product manufacturing and operating costs | (13) |
| 9.3 | Advertising and marketing | (11) |
| 9.4 | Leased assets | - |
| 9.5 | Staff costs | (580) |
| 9.6 | Administration and corporate costs | (625) |
| 9.7 | Other (provide details if material) | - |
| **9.8** | **Total estimated cash outflows[1]** | **(1,669)** |

[1] On 10 July 2019, the Company announced a capital raise, totalling $4,020,000. On 19 July 2019, the Company completed Tranche 1 of the capital raising which raised $350,000 (before costs).

| 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 July 2019
(Director/Company Secretary)

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.