

# ASX Half-Yearly Report to 31 December 2018

Lodged with the ASX under Listing Rule 4.2A

The information provided in this Half-Yearly Report should be read in conjunction with the Company's 2018 Annual Financial Report.

# RESULTS FOR ANNOUNCEMENT TO THE MARKET

#### **SUMMARY RESULTS FOR THE 6 MONTHS ENDED 31 DECEMBER 2018**

The following is a summary of the financial results for the 6 months ended 31 December 2018 (previous corresponding period 31 December 2017).

#### I. SUMMARY RESULTS

	Increase/ (Decrease) %	Six months ended 31 December 2018 \$	Six months ended 31 December 2017 \$
Revenue from ordinary activities	11%	3,415,770	3,066,469
(Loss)/Profit from ordinary activities after tax attributable to members	(29)%	(4,018,145)	(5,670,587)
(Loss)/Profit for the period attributable to members (NPAT)	(29)%	(4,018,145)	(5,670,587)

#### 2. DIVIDENDS

No interim dividend has been declared for the current and previous reporting period. There are no dividend reinvestment plans in operation.

# 3. EARNINGS/ (LOSS) PER SHARE (EPS)

	31 December 2018	31 December 2017
Basic and diluted loss per share	(1.97) cps	(3.36) cps
Weighted average number of shares used in the calculation of basic EPS	202,628,271	168,792,889

The amount used in the numerator in calculating basic EPS is the same as the net profit reported in the consolidated statement of profit or loss.

#### 4. NET TANGIBLE ASSET BACKING

	31 December 2018	31 December 2017
Net tangible asset backing per ordinary share	13.55 cents	6.39 cents

# 5. CONTROL GAINED OR LOST OVER ENTITIES

Not applicable.

# 6. DETAILS OF ASSOCIATES AND JOINT VENTURE ENTITIES

Not applicable.

## 7. FOREIGN ENTITIES

Not applicable.

# 8. AUDIT QUALIFICATION OR REVIEW

The accounts (attached) are not subject to dispute or qualification. This report is based on accounts that have been subject to a review. The entity has a formally constituted audit committee.

# 9. ATTACHMENTS

The Half Year Report for the six months ended 31 December 2018 is attached.

### 10. SIGNED

Date: 28 February 2019

Signed\_

David B. Kaysen

Chairman, CEO and Managing Director

# medibio

# 31 DECEMBER 2018

Provided in accordance with Section 320 of the Corporations Act (2001).



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# **Corporate Information**

**Directors** 

D Kaysen - Chairman, Managing Director & CEO

P Carlisle - Non-Executive & Lead Independent Director

F Prendergast - Non-Executive Director

M Phelps – Non-Executive Director

P Kennedy - Non-Executive Director

C Solitario - Non-Executive Director

M Leydin - Director

**Company Secretaries** 

M Leydin and M Watkins

**Registered Office** 

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**Share Register** 

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Facsimile: +61 3 9473 2500

**Internet Address** 

www.medibio.com.au

**Auditors** 

William Buck (QLD)

Level 21, 307 Queen Street

Brisbane, QLD 4000

**Bankers** 

Westpac Banking Corporation

Home Exchange

**ASX Limited** 

20 Bridge Street

Sydney NSW 2000



# **Directors' Report**

The Directors submit the financial report of Medibio Limited ('MEB' or 'Medibio') and its controlled entities for the half-year ended 31 December 2018.

#### **DIRECTORS**

The names of the directors who held office during or since the end of the half-year and up to the date of this report are:

David Kaysen Chairman, Managing Director & CEO (appointed 5 November 2018)

Peter Carlisle Non-Executive & Lead Independent Director (appointed Lead

Independent Director effective 22 February 2019)

Frank Prendergast Non-Executive Director
Michael Phelps Non-Executive Director
Patrick Kennedy Non-Executive Director

Claude Solitario Non-Executive Director (appointed 31 December 2018)

Melanie Leydin Director (appointed 22 February 2019)

Chris Indermaur Non-Executive Chairman (resigned 31 December 2018)

Andrew Maxwell Non-Executive Director (resigned 22 February 2019)

Jack Cosentino Managing Director & CEO (resigned 20 September 2018)

# **REVIEW AND RESULTS OF OPERATIONS**

# **Financials**

# Results

During the six months to 31 December 2018, the Company recorded a loss of \$4,018,145 (2017 – loss \$5,670,587).

The loss for the period reflected the following:

- costs associated with the development of the Company's technology for use of objective biometrics to assist in the screening, diagnosing, monitoring, and management of depression and other mental health conditions;
- operating corporate and administrative overheads.

### Statement of financial position

Key factors to note from the statement

 cash decreased by \$4 million due to employee severance and other associated costs, and operating activities that occurred during the period.



# **Directors' Report (continued)**

# **Review and results of operations** (continued)

### **Operations**

During the half year, the Company made significant progress in product refinement and commercialisation strategy of its mental health technology platform. Highlights include:

# **Quality and Regulatory Advancement**

- Submitted FDA De Novo application
- Announced clinical study results showing an improvement of more than 20% relative to the current diagnostic standard
- Received FDA's initial response to De Novo submission; began work needed for detailed response.
- Identified 501(k) as parallel regulatory path

# **Corporate Development**

- Lindsey Hagan joined the Company as VP, Integrated Health. As of 15 January, Ms Hagan's title was changed to VP of Strategy and Business development to reflect her expanded role and responsibilities in leading corporate strategy and business development for the regulatory pathway and commercialisation
- Launched ilumen<sup>™</sup> corporate health product
  - Announced contracts with AIAA and others for pilot programs

#### Scientific & Technical Advancement

- Medibio Chief Medical Officer, Archie Defillo MD, presented two clinical abstracts at Mayo Clinic Conference
- Scientific Advisory Board held second meeting

#### **Management Update**

- Jack Cosentino, Managing Director and CEO, ceased employment 28 August 2018
- Peta Slocombe, SVP Corporate Health, ceased employment
- Appointed Jennifer Solitario, SVP Corporate Health
- David B. Kaysen, global healthcare leader, named Managing Director and CEO

### **Board and Board-Related Matters**

- Appointment of Peter Carlisle as Vice-Chairman 31 August 2018; named Interim Chairman
   31 December 2018, ceased as Interim Chairman 22 February 2019 and appointed as Lead Independent Director
- Announced changes to board 31 December 2018



# **Directors' Report (continued)**

# Review and results of operations (continued)

### **Financial and Capital Highlights**

- Announced significant cost-reduction plans in both the U.S. and Australia.
- Received R&D tax incentive refund of \$3.1 million
- Announced convertible note and non-renounceable entitlement offer

### **COMPANY UPDATE**

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Post balance date, The Company released an updated investor presentation 15 February 2019.

On 5 November 2018, the Company welcomed David B. Kaysen in the CEO and Managing Director role.

# **QUALITY & REGULATORY ADVANCEMENT**

In September, the Company announced results from its confirmatory clinical study evaluating the accuracy of its DDA algorithm. Results showed statistical accuracy of the algorithm to detect a Major Depressive Episode (MDE). This validation is a milestone in the Company's development of an objective test for aiding in the diagnosis of depression in patient care.

Key benefits of the clinical study results include:

- 1. Demonstration of effectiveness as an adjunctive diagnostic aid.
- 2. Accuracy of 70% with 70% sensitivity and 71% specificity.
- 3. Results indicated 20-40% improvement from current diagnostic standard. [1][2][3][4]
- 4. Patent-pending algorithm provides sophisticated and accurate measurements; potential for long-term monitoring of mental disorders.
- 5. Study targeted general population in a normal-daily-home environment.
- 6. Generate academic work and scientific publications in support of the FDA De Novo submission.

The technology is a step forward in the search for objective digital biomarkers of depression and other mental illnesses supported by clinical prediction models, taking into consideration that inter-rater disagreement is common in mental health conditions. Medical benefits of the Medibio algorithm is the improvement of diagnostic sensitivity and specificity, and reduction of under-diagnosis, as compared to patients who only received clinical assessments. The results provided further validation of Medibio's proposition that psychiatric conditions differentially affect the autonomic nervous system (ANS), resulting in anomalies of cardiac and sleep functions. Medibio's algorithm distinguished accurately between individuals with MDE and non-depressed controls in 70%-71%.

# medibio

ABN: 58 008 130 336

# **Directors' Report (continued)**

# **Review and results of operations** (continued)

The algorithm is designed to provide mental health practitioners with an objective technology to aid in assessment of MDE. These results are superior to known depressive inter-rater agreement values that range from 0.64-0.48<sup>1,2,3,4</sup>.

Following release of our results, we hosted a teleconference to discuss the findings and answer investor questions in a transparent approach inviting involvement in the clinical process. Topics included the importance of the study to Medibio's technology, a general overview of the study and results, supporting methodology, and comparison to prior studies.

Medibio received the FDA's response to our De Novo application submission filed July 2018. The response requests clarification on 11 key points, including study methodology, intent of use, labelling and cybersecurity. This is an expected and complex process and our team has begun gathering the required information to provide the FDA a detailed response within their designated timeframe, no later than 29 April 2019.

Parallel to that effort, Medibio will concentrate on reviewing and achieving other regulatory avenues for one or more current modules which address various mental health conditions. We believe we are in a position to submit one or more 510(k) application(s) to the FDA. The 510(k) process is a more common route, which should provide us with FDA clearance for specific pipeline products within the first half of 2019. We expect to implement a commercialisation strategy in the U.S., based on 510(k) clearance, by end of 2019 calendar year.

<sup>[1]</sup> Mulsant BH., et al. Interrater reliability in clinical trials of depressive disorders. AM J Psychiatry. 2002 Sept: 159(9): 1598-1600

<sup>[2]</sup> Lieblich Samuel, et.al. High heterogeneity and low reliability in the diagnosis of major depression will impair the development of new drugs: BJPsych Open (2015) 1, e5–e7.

<sup>[3]</sup> Cairney J., et al. Evaluation of 2 measures of psychological distress as screeners for depression in the general population. The Canadian Journal of Psychiatry 2007 Feb: Vol 52(2).

<sup>[4]</sup> Einfeld S., et al. Inter-Rater Reliability of the Diagnoses of Psychosis and Depression in Individuals with Intellectual Disabilities: 2007 Sept: 20 (5): 384-390



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# **Directors' Report (continued)**

# **Review and results of operations** (continued)

#### CORPORATE DEVELOPMENT

Lindsey Hagan joined Medibio as VP of Integrated Health Systems in September to partner with the technology and clinical teams on product strategy and lead business development initiatives. Ms Hagan has more than 13 years of sales experience working with medical device, technology, pharmaceutical, and healthcare organizations. With the company's increased efforts to refine business and product strategy, Ms Hagan's title was changed to VP of Strategy and Business Development to better reflect her role in leading strategy and business development for all regulated products and develop future commercialisation efforts.

In October 2018, we launched ilumen<sup>™</sup>, our second Corporate Health product, to coincide with Australia's Mental Health Month and World Mental Health Day. A unique solution for corporate health programs seeking to offer support for mental wellness, ilumen<sup>™</sup> provides participants with a two-part system for checking and monitoring symptoms of depression, anxiety, and stress. Coupling Medibio's key biometric data and a subjective assessment, users get a 'wellness snapshot' they can track and improve upon over time. Employers have access to a de-identified, aggregate-level dashboard to support informed decision making, improved team performance, and increased employee well-being. Many companies have healthcare plans in place to address physical health; Medibio's platform allows employers to extend support to mental health.

A contract signed by a large Australian employer provided access to ilumen<sup>™</sup> to 8,000 personnel over a six-week engagement. The pilot commenced in October 2018 and was completed on 7 December 2018 with significant participation from employees of the organization. In November, Medibio announced that it has signed an exclusive agreement with AIAA to undertake a pilot program with ilumen<sup>™</sup>. AIAA will have access to ilumen<sup>™</sup> over a six-month period for its Australia and New Zealand employees. The contract commenced in November with full pilot expected to commence in March 2019.

The Company continues to respond to inquiries and conduct exploratory meetings with a number of global organizations based in Australia to follow up on interest in ilumen<sup>TM</sup>.

### **SCIENTIFIC & TECHNICAL ADVANCEMENT**

Two clinical abstracts by Defillo et al. were selected for presentation as part of the Mayo Clinic Convergence Neuroscience 2018 Course. Both presentations were based on Medibio's technology, the algorithm and DX04 clinical study. Dr. Defillo shared the following abstract presentations during the event November 8-10, 2018:

- I. A Machine Learning Based Approach to Identify Heart Rate Variability Patterns Serving as a Diagnostic Aid for Major Depressive Episodes.
- 2. A Novel Technology in Mental Health Variations in Cardio-Autonomic Function Used as Diagnostic Support for Major Depressive Episodes.



# **Directors' Report (continued)**

# **Review and results of operations** (continued)

Medibio's Scientific Advisory Board held its second meeting in December 2018 to review and discuss the DX04 findings related to current FDA De Novo submission. The Advisory Board discussed and advised on next steps in the regulatory process.

#### MANAGEMENT UPDATE

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From 28 August 2018, Jack Cosentino ceased as CEO and Managing Director and as a Director from 20 September 2018.

Also, in September, the Company appointed Jennifer Solitario as Senior Vice President of Corporate Health. Ms Solitario is a proficient leader with more than 20 years of experience in the health insurance industry and brings proven and extensive contract negotiation skills. Ms Solitario is located in the Company's Perth office. She joined the Company upon departure of Peta Slocombe, formerly SVP Corporate Health.

In November, Medibio welcomed David B. Kaysen as CEO and Managing Director. Mr Kaysen brings more than 35 years of experience leading and managing both domestic and international emerging growth companies. He has achieved consistent and solid results with biopharmaceutical, medical device, and clinical software/IT companies. Mr Kaysen is experienced in the FDA approval process, leading products to revenue growth, and has experience in Australia.

### **BOARD AND BOARD-RELATED MATTERS**

The following leadership changes were announced in December:

- From 31 December 2018, Mr. Christopher Indermaur ceased as Non-Executive Chairman of the Company in order to focus on other business interests.
- Mr Peter Carlisle was appointed as Interim Chairman of the Board from 31 December 2018 until a new Chairman is elected by the Board (which occurred following the end of the period).
- Mr Claude Solitario was appointed as a Non-Executive Director of the Company from 31
  December 2018. Mr Solitario brings 30 years of experience in the development of new and
  emerging technology, with a deep understanding of licensing and commercialisation of
  intellectual property. He is a founding shareholder of Medibio Ltd and one of its major
  shareholders. Mr Solitario also brings extensive financial background having served as a
  financial executive for many public and private companies.



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# **Directors' Report (continued)**

# **Review and results of operations** (continued)

### FINANCIAL AND CAPITAL HIGHLIGHTS

Announced significant cost reduction plans in both the U.S. and Australia. With these plans, projected monthly average cash burn Feb to Dec 2019 is \$485,000.

The Company has also implemented a redundancy program eliminating certain staff positions in its Perth, Australia offices.

Effective I January 2019, the Non-Executive Directors will no longer receive any cash compensation for their services. The Board intends to implement an equity-based compensation plan for all Non-Executive Directors for their services.

Effective I January 2019, Brian Mower ended his tenure as the Company's CFO. At that time, the Company Controller, Steve Sathre, took on the role of interim CFO. As of 8 February 2019, Mr Sathre ended his tenure with the Company, accepting a position with another organisation. From II February 2019, Ms Peggy Morgan has been named Corporate Controller.

The Company is mindful of its cash position and have taken cost-reduction actions, including termination of vendor contracts and reduction in staff, to reduce net future quarterly cash outlays. The Company will continue to evaluate spending at all levels of the organisation while maintaining an adequate infrastructure to support organizational goals.

In October, the Company received \$3,146,835 from the Australian Taxation Office under the Research and Development Tax Incentive Program. The cash refund is related to expenditure on eligible R&D activities conducted during the financial year ended 30 June 2018. The Company received firm commitments from sophisticated and professional investors to subscribe for approximately 125,000,000 Convertible Notes at \$0.02 per note (Notes) under which the Company will receive approximately \$2.5 million, before set-offs and issuance costs, in two tranches under a Convertible Note Deed Poll. (Convertible Note Deed Poll). The first tranche was received in December 2018 and the second tranche was received in January 2019.

The Company also announced a non-renounceable pro-rata rights issue of I fully paid ordinary share (New Share) for each I Share held by eligible shareholders seeking to raise approximately \$4.05 million (Entitlement Offer) before issuance costs. The proceeds from the issue of Notes and shareholder participation in the Entitlement Offer will be used to fund the costs of the Entitlement



# **Directors' Report (continued)**

# **Review and results of operations** (continued)

Offer, advance its 510(k) regulatory approval, progress its De Novo submission, technology development, product commercialisation and for the Company's working capital requirements.

The Entitlement Offer is expected to close in March 2019. The Company's cash position at 31 December 2018 was A\$2.2 million. In December 2018, the Company received approximately A\$0.5 million (net of issuance costs) upon the issuance of approximately 30 million first-tranche convertible notes under the Convertible Note Deed Poll mentioned above. The remaining cash inflows of approximately A\$0.2 million were from customers' payments, GST refunds and interest payments.

The Company had A\$4.5 million cash outflows during the first two quarters of the fiscal year. The comparative increase in cash spent reflects the Company's renewed focus on core activities and the impact of cost reduction strategies discussed above. These strategies are expected to result in a projected monthly average cash burn of \$485,000 for the period of February to December 2019. The remaining expenditures were related to recurring business activities, including the development of products and expenses incurred for regulatory filings.

As at 31 December 2018, Medibio has 4,650,000 partly paid contributing shares (with 29 cents to pay). The Directors are reviewing various options to address these partly paid contributing shares and plan to come to a resolution no later than 30 June 2019.

### EVENTS SUBSEQUENT TO BALANCE DATE

Since 31 December 2018, the Company has issued 107,272,280 convertible notes at \$0.02 per note, raising \$2,145,446.

#### AUDITOR'S INDEPENDENCE DECLARATION

The lead auditor's independence declaration for the half-year ended 31 December 2018 under s 307C of the Corporations Act 2001, is set out on page 12.

This report is signed in accordance with a resolution of the Board of Directors:

David B. Kaysen

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Chairman, CEO and Managing Director

Date 28 February 2019

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# **Auditor's Independence Declaration**

As lead auditor for the review of Medibio Limited for the half-year ended 31 December 2018, I declare that, to the best of my knowledge and belief, there has been:

- (a) no contravention of the auditor independence requirements of the *Corporations Act 2001* in relation to the review; and
- (b) no contravention of any applicable code of professional conduct in relation to the review.

This declaration is in respect of Medibio Limited and the entities it controlled during the period.

William Buch

William Buck (Qld) ABN 21 559 713 106

M. Mory L

M J Monaghan Director

Brisbane: 28 February 2019

CHARTERED ACCOUNTANTS & ADVISORS

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williambuck.com



# Consolidated Statement of Profit or Loss and Other Comprehensive Income

# FOR THE HALF-YEAR ENDED 31 DECEMBER 2018

	Note	31 December 2018	31 December 2017
		\$	\$
Revenues	2		
Sales		268,935	53,498
Contract milestone achievement		-	226,000
Other income		3,146,835	2,786,971
		3,415,770	3,066,469
Expenses	3		
Amortisation		-	(858,503)
Finance costs		(5,550)	(3,403)
Employee costs		(3,663,601)	(2,531,230)
Research & development		(135,837)	(1,536,644)
Other expenses		(3,598,104)	(3,807,276)
Loss before income tax		(3,987,322)	(5,670,587)
Income tax		-	-
Loss attributable to members of Medibio Limited		(3,987,322)	(5,670,587)
Items that may be reclassified subsequently to profit or loss			, , , , , , , , , , , , , , , , , , ,
Foreign Currency Translation		(30,823)	-
Total comprehensive loss attributable to members of Medibio Limited		(4,018,145)	(5,670,587)
Loss per share			
Basic & diluted loss per share (cents per share)		(1.97)	(3.36)
•			

The above consolidated statement of profit or loss and other comprehensive income should be read in conjunction with the accompanying notes.

# **Consolidated Statement of Financial Position**

# **AS AT 31 DECEMBER 2018**

	Notes	31-Dec 2018 \$	30-June 2018 \$
ASSETS			_
Current Assets			
Cash and cash equivalents		2,150,793	6,123,187
Trade and other receivables		1,451,178	1,669,026
Prepayments		142,539	93,954
Total Current Assets		3,744,510	7,886,167
Non-current Assets			
Other assets		111,751	111,186
Intangible assets	4	11,093,336	11,066,885
<b>Total Non-current Assets</b>		11,205,087	11,178,071
TOTAL ASSETS		14,949,597	19,064,238
LIABILITIES			
<b>Current Liabilities</b>			
Trade and other payables		4,116,309	3,969,225
Borrowings	5	120,000	120,000
Employee Liabilities		154,031	988,525
<b>Total Current Liabilities</b>		4,390,340	5,077,750
Non-current Liabilities			
Borrowings	5	550,248	-
Total Non-current Liabilities		550,248	-
TOTAL LIABILITIES		4,940,588	5,077,750
NET ASSETS		10,009,009	13,986,488
EQUITY			
Issued capital	6	83,642,250	83,642,250
Reserves		4,266,343	4,256,500
Accumulated losses		(77,899,584)	(73,912,262)
TOTAL EQUITY		10,009,009	13,986,488

The above consolidated statement of financial position should be read in conjunction with the accompanying notes.

# Consolidated Statement of Changes in Equity FOR THE HALF-YEAR ENDED 31 DECEMBER 2018

	Issued Capital	Foreign Currency Translation Reserve	Accumulated Losses	Share Based Payments Reserve	Total Equity
_	\$		\$	\$	\$
At 1 July 2017	68,999,845	-	(58,071,851)	2,386,086	13,314,080
Comprehensive income			(		( <u>)</u>
Loss for the period	-	-	(5,670,587)	-	(5,670,587)
Other comprehensive income	-	-	-	-	-
Total comprehensive income	-	-	(5,670,587)	-	(5,670,587)
Transactions with owners					
Shares issued	16,126,976	-	-	-	16,126,976
Share options issued	-	-	-	1,048,222	1,048,222
Share issue costs	(1,672,334)	-	-	620,794	(1,051,540)
Total transactions with owners	14,454,642	-	-	1,669,016	16,123,658
At 31 December 2017	83,454,487	-	(63,742,438)	4,055,102	23,767,151
At 1 July 2018	83,642,250	(132,274)	(73,912,262)	4,388,774	13,986,488
Comprehensive income			(0.007.000)		(0.007.000)
Loss for the period	-	(00,000)	(3,987,322)	-	(3,987,322)
Other comprehensive income	-	(30,823)	-	-	(30,823)
Total comprehensive income	-	(30,823)	(3,987,322)	-	(4,018,145)
Transactions with owners Foreign currency movements	_			40,666	40,666
Total transactions with owners	-	-	-	40,666	40,666
At 31 December 2018	83,642,250	(163,097)	(77,899,584)	4,429,440	10,009,009

The above consolidated statement of changes in equity should be read in conjunction with the accompanying notes.

# **Consolidated Statement of Cash Flows**

# FOR THE HALF-YEAR ENDED 31 DECEMBER 2018

	31 December 2018 \$	31 December 2017 \$
Cash flows from operating activities		
Receipts from customers	419,402	5,185
R&D grant/rebate received	3,146,835	3,266,998
Contract milestone achievement	-	226,000
Payments to suppliers and employees	(8,107,110)	(7,143,492)
Net cash flows used in operating activities	(4,540,873)	(3,645,309)
Cash flows from investing activities Interest received	18,231	19,973
Net cash flows generated from investing activities	18,231	19,973
Cash flows from financing activities Proceeds from issue of shares/convertible notes Repayment of shareholder loan Payments for share issue costs	550,248 - -	14,795,190 (12,500) (1,051,540)
Net cash flows generated from financing activities	550,248	13,731,150
Net increase in cash and cash equivalents	(3,972,394)	10,105,814
Cash and cash equivalents at beginning of period	6,123,187	5,010,052
Cash and cash equivalents at end of period	2,150,793	15,115,866

The above consolidated statement of cash flows should be read in conjunction with the accompanying notes.

#### I. BASIS OF PREPARATION

These general-purpose financial statements for the interim half-year reporting period ended 31 December 2018 have been prepared in accordance with the requirements of the *Corporations Act* 2001 and Australian Accounting Standards including AASB 134: Interim Financial Reporting.

These interim financial statements are intended to provide users with an update on the latest annual financial statements of Medibio Limited and its controlled entities (the consolidated entity). As such, it does not contain information that represents relatively insignificant changes occurring during the half-year within the consolidated entity. It is therefore recommended that these financial statements be read in conjunction with the annual financial statements of the consolidated entity for the year ended 30 June 2018, together with any public announcements made since 1 July 2018.

The same accounting policies and methods of computation have been followed in these interim financial statements as were applied in the most recent annual financial statements, except for the effects of the below.

The consolidated entity has adopted all of the new and revised pronouncements which became mandatory for annual reporting periods beginning on or after I July 2018. In adopting these new and revised pronouncements, the consolidated entity has determined that there has been no impact to the consolidated entity's reported position or performance.

#### **AASB 15 Revenue from Contracts with Customers**

The Group has adopted AASB 15 as issued in May 2014 with the date of initial application being I July 2018. In accordance with the transitional provisions in AASB 15 the standard has been applied using the full retrospective approach. In this regard, the Group applied a practical expedient and did not restate any contract that were completed at the beginning of the earliest period presented.

AASB 15 supersedes AASB 18 Revenue, AASB 111 Construction Contracts and related interpretations and it applies to all revenue arising from contracts with customers, unless those contracts are in the scope of other standards. The new standard establishes a five-step model to account for revenue arising from contracts with customers. Under AASB 15, revenue is recognised at an amount that reflects the consideration which an entity expects to be entitles in exchange for transferring goods or services to a customer.

Revenue accounting policy – rendering of services

Revenue from a contract to provide services is recognised over time as the services are rendered based on either a fixed price or an hourly rate.

# **AASB 9 Financial Instruments**

The group has adopted AASB 9 as issued in July 2014 with the date of initial application being I July 2018. In accordance with the transitional provisions in AASB 8, comparative figures have not been restated. AASB 9 replaces AASB 39 Financial Instruments: Recognition and Measurement, bringing together all three aspects of the accounting for financial instruments: classification and measurement; impairment; and hedge accounting.

### Measurement and classification

Under AASB 9, debt instruments are subsequently measured at fair value through profit or loss (FVTPL), amortised cost, or fair value through other comprehensive income (FVOCI). The classification is based on two criteria: the Group's business model for managing the assets; and whether the instruments' contractual cash flows represent 'solely payments of principal and interest' on the principal amount outstanding (the SPPI criterion). The SPPI test is applied to the entire financial asset, even if it contains an embedded derivative. Consequently, a derivative embedded in a debt instrument is not accounted for separately.

At the date of initial application, existing financial assets and liabilities of the Group were assessed in terms of the requirements of AASB 9. The assessment was conducted on instrument that had not been derecognised as at 1 July 2018. In this regard, the Group has determined that the adoption of AASB 9 has impacted the classification of financial instruments at 1 July 2018 as follows:

Cash and cash equivalent, trade and other receivables and other assets which were previously classified as loans and receivables, are now classified as financial assets at amortised cost, from I July 2018. The change in classification has not resulted in any re-measurement adjustments at I July 2018.

### **GOING CONCERN STATEMENT**

As at 31 December 2018, the Group had a net asset position of \$10,009,009 (30 June 2018: \$13,986,488). However, as at 31 December 2018 it had:

- Incurred a loss for the period of \$4,018,145 (31 December 2017: \$5,670,587)
- Net cash outflows from operations of \$4,540,873 (31 December 2017: \$3,645,309)
- Cash at bank of \$2,150,793 (30 June 2018: \$6,123,187)
- Current liabilities exceed current assets by \$645,830. (30 June 2018: \$2,808,417 assets exceeded liabilities)

The Directors have assessed the Group's operating and research costs along with future research and development activities in order to establish future funding requirements. Based on this assessment there are indications that current working capital may not be sufficient to enable the Group to carry out planned operations. As such, the Group's ability to continue as a going concern is dependent upon the generation of cash from operations, the sufficiency of current cash reserves to meet existing obligations, the ability to reschedule planned research and development activity, raising of further equity through shares and convertible notes, and receipt of research and development tax incentives.

In December 2018, Medibio Limited closed on 30 million in first tranche convertible notes, netting \$550,248 after issuance costs and debt reduction. A second tranche netting \$1,791,952 closed in January 2019. The Directors of Medibio Limited are confident that the Company is able to raise further equity from its shareholders and sophisticated and professional investors, if required.

On 10 December 2018, the Company announced a Non-Renounceable pro-rata Entitlement Offer of I fully paid ordinary share for each I Share held by eligible shareholders at the record date to raise up to \$4.05 million (before costs). It is currently anticipated that the offer will close on 7 March 2019.

Accordingly, the Directors believe the Group will be able to pay its debts as and when they fall due for a period of at least 12 months from the date of these financial statements.

	31 December 2018	31 December 2017
	\$	\$
2. REVENUE		
Sales	250,704	53,498
Contract milestone achievement	-	226,000
Interest received	18,231	19,973
R&D grant/rebate, net of allowance	3,146,835	2,766,998
Total Revenue	3,415,770	3,066,469
3. EXPENSES		
(i) Finance costs		
Leasing costs	5,550	3,403
	5,550	3,403
(ii) Employee benefits expense		
Wages and salaries	3,453,532	2,267,238
Directors' fees	210,069	263,992
	3,663,601	2,531,230
(iii) Other expenses		
Consulting and advisory expenses	1,109,187	1,401,277
Legal fees	1,009,579	172,466
Listing fees	37,333	137,070
Share registry	10,343	14,123
Sales and marketing	117,356	241,561
Other administrative expenses	1,314,306	1,840,779
	3,598,104	3,807,276

	31 December 2018	30 June 2018
	\$	\$
INTANGIBLE ASSETS		
Licence		
Heartlink Limited		
At cost	300,000	300,000
Accumulated Amortisation	(300,000)	(300,000)
Net carrying amount	-	-
Development Costs		
At cost	2,984,709	2,782,317
Foreign currency changes to asset cost	26,451	19,192
Additions	-	183,200
Accumulated amortisation	(21,567)	(21,567)
Net carrying amount	2,989,593	2,963,142
Patents		
At cost	4,498,153	4,498,153
Additions	-	-
Accumulated Amortisation	(4,498,153)	(4,498,153)
Net carrying amount	-	<u>-</u>
Data files		
At cost	7,794,643	7,794,643

Net carrying amount

7,794,643

7,794,643

	31 December 2018 \$	30 June 2018 \$
4.INTANGIBLE ASSETS (continued)		
Goodwill		
At cost	754,099	754,099
Accumulated impairment losses	(444,999)	(444,999)
Net carrying amount	309,100	309,100
Net carrying amount at beginning of year  Foreign currency changes to asset cost  Additions  Amortisation	11,066,885 26,451 - -	11,884,855 19,192 492,300 (1,329,462)
Net carrying amount	11,093,336	11,066,885
5.BORROWINGS  Current – shareholders loan	120,000	120,000
Non-current - Convertible notes	550,248	_

On 18 December 2018, the Group issued a total of 30,394,240 Convertible Notes at an issue price of \$0.02 (2 cents) per Note. Key terms attaching to the note:

- Conversion is at the holder's discretion up to the maturity date, when all remaining notes will be automatically converted
- Converted at the lower of \$0.02 and the issue price per share under any subsequent equity capital raising undertaken by Medibio during the conversion period
- Maturity date of the notes is 18 months after issue
- Under the terms of the Convertible Note Deed, there is no option for Medibio to repay the
  noteholders in cash, except in an insolvency event. However, as there is the potential under the
  Convertible Note Deed for a variable number of shares to be issued, the value of the convertible
  notes issued as at 31 December 2018 are classified as a liability until they are converted into shares

	31 December 2018	30 June 2018
6. ISSUED CAPITAL		
Issued and paid up capital		
Issued and fully paid	\$83,642,250	\$83,642,250
Number of shares on issue at reporting date	202,628,271	202,628,271
Number of partly paid shares on issue at		
reporting date	4,650,000	4,650,000
Number of options on issue at reporting date	33,012,113	45,862,113

### 7. OPERATING SEGMENTS

The consolidated entity has one operating segment, being the research, development and commercialisation of its Software as a Service product, and one geographical location, being Australia. It maintains a US based subsidiary to support US and Canadian research and development activities.

#### 8. COMMITMENTS AND CONTINGENCIES

There were no changes in the consolidated entity's commitments and contingencies since 30 June 2018.

### 9. EVENTS AFTER THE END OF THE REPORTING PERIOD

Since 31 December 2018, the consolidated entity has issued 107,272,280 convertible notes at \$0.02 per note, raising \$2,145,446 (before issuance costs and debt reduction).

# 10. FAIR VALUE

The directors consider that the carrying amounts of financial assets and financial liabilities recognised in the consolidated financial statements are reasonable approximation of their fair value.

# **Directors' Declaration**

In accordance with a resolution of the directors of Medibio Limited, I state that:

In the opinion of the directors:

- 1. the financial statements and notes of the consolidated entity are in accordance with the *Corporations Act 2001*, including:
  - a. giving a true and fair view of the financial position as at 31 December 2018 and of its performance for the half-year ended on that date; and
  - b. complying with the Accounting Standard AASB 134 "Interim Financial Reporting" and the Corporations Regulations 2001.
- 2. there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

On behalf of the Board

David B. Kaysen

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Chairman, CEO and Managing Director

28 February 2019



# **Medibio Limited**

Independent auditor's review report to members

# Report on the Review of the Half-Year Financial Report

#### Conclusion

We have reviewed the accompanying half-year financial report of Medibio Limited (the company) and the entities it controlled at the half-year's end or from time to time during the half year (the consolidated entity) on pages 11 to 23, which comprises the consolidated statement of financial position as at 31 December 2018, the consolidated statement of profit or loss and other comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the half-year ended on that date, notes comprising a summary of significant accounting policies and other explanatory information, and the directors' declaration.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the half-year financial report of Medibio Limited on pages 11 to 23 is not in accordance with the Corporations Act 2001 including:

- a) giving a true and fair view of the consolidated entity's financial position as at 31
   December 2018 and of its performance for the half year ended on that date; and
- complying with Australian Accounting Standard 134 Interim Financial Reporting and the Corporations Regulations 2001.

# **Material Uncertainty related to Going Concern**

We draw attention to Note 1 in the financial report, which indicates that the consolidated entity incurred a loss of \$4,018,145 (31 December 2017: \$5,670,587) and had net cash outflows from operations of \$4,540,873 (31 December 2017: \$3,645,309) during the half year ended 31 December 2018. As stated in Note 1, these events or conditions, along with other matters as set forth in Note 1, indicate that a material uncertainty exists that may cast significant doubt on the consolidated entity's ability to continue as a going concern. Our conclusion is not modified in respect of this matter.

### Responsibilities of the Directors' for the Half-Year Financial Report

The directors of the company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the Corporations Act 2001 and for such internal control as the directors determine is necessary to enable the preparation of the half-year financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

# CHARTERED ACCOUNTANTS & ADVISORS

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# Auditor's Responsibilities for the Review of the Half-Year Financial Report

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE 2410 Review of a Financial Report Performed by the Independent Auditor of the Entity, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the financial report is not in accordance with the Corporations Act 2001 including:

- giving a true and fair view of the consolidated entity's financial position as at 31
   December 2018 and its performance for the half-year ended on that date; and
- complying with Accounting Standard AASB 134 Interim Financial Reporting and the Corporations Regulations 2001.

As the auditor of Medibio Limited, ASRE 2410 requires that we comply with the ethical requirements relevant to the audit of the annual financial report.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

### Independence

In conducting our review, we have complied with the independence requirements of the Corporations Act 2001. We confirm that the independence declaration required by the Corporations Act 2001, which has been given to the directors of Medibio Limited, would be in the same terms if given to the directors as at the time of this auditor's review report.

William Buch

William Buck (Qld)

ABN: 21 559 713 106

M J Monaghan

M. Mory

Brisbane 28 February 2019