

20 February 2020

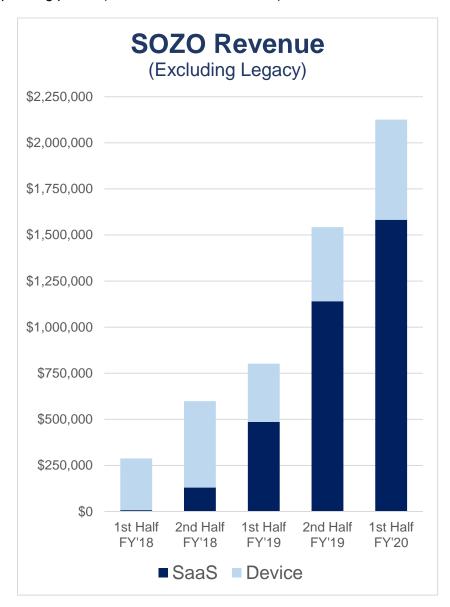
### **ASX ANNOUNCEMENT**

## APPENDIX 4D - Half-Year Results Ended 31 December 2019

**Brisbane, Australia** – ImpediMed Limited (ASX.IPD), a medical software technology company that non-invasively measures, monitors and manages fluid status and tissue composition using bioimpedance spectroscopy (BIS), today released its Appendix 4D and interim financial results for the half-year ended 31 December 2019 (1st Half FY'20).

# **Key Financial and Operational Summary:**

- Total Revenue for 1<sup>st</sup> Half FY'20 of \$2.8 million, up 56% from the previous corresponding period (1<sup>st</sup> Half FY'19: \$1.8 million).
- SOZO<sup>®</sup> SaaS Revenue for 1<sup>st</sup> Half FY'20 of \$1.6 million, up 220% from the previous corresponding period (1<sup>st</sup> Half FY'19: \$0.5 million).

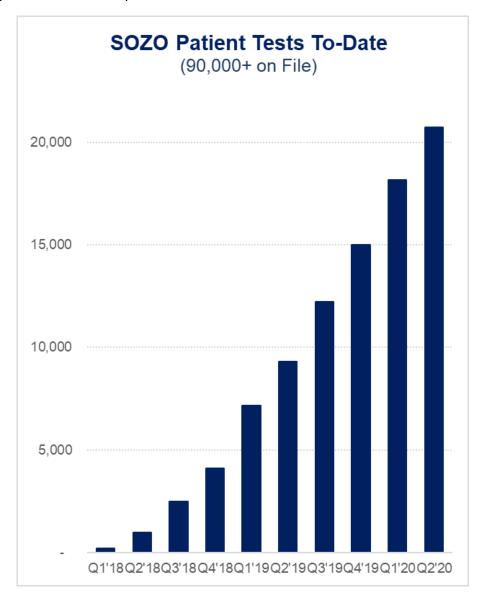




- Contracted Revenue Pipeline<sup>i</sup> up 37% from the previous corresponding period to \$9.6 million (31 December 2018: \$7.0 million).
- Annual Recurring Revenue<sup>ii</sup> up 68% from the previous corresponding period to \$4.2 million (31 December 2018: \$2.5 million).
- A total of more than 480 SOZO units have been sold since launch, up 51% from the previous corresponding period (31 December 2018: 317 SOZO units).
- The customer churn rate remains negligible at less than 0.5%.
- 100% renewal rate on expiring SOZO contracts.
- Cash on hand as at 31 December 2020 of \$13.0 million (30 June 2019: \$11.3 million).
- Net operating cash outflow of \$9.8 million (31 December 2018: \$9.4 million).

## **Detailed Operational Highlights:**

• As of 31 December 2019, the total patient tests on file were over 90,000, demonstrating the growing awareness of the importance of lymphoedema prevention and adoption of SOZO.



 As of today, SOZO customers have now collectively taken over 100,000 patient measurements since commercial launch in October 2017. More than 38,000 patient tests were conducted in the last six-months alone.



- The Company launched the Lymphoedema Prevention Program, a program aimed at ending cancer-related lymphoedema. This comprehensive initiative utilises ImpediMed's Test, Trigger, Treat™ protocol for early detection and intervention of cancer-related lymphoedema. Although early into its launch, the Company is already seeing promising signs of success. Device sales into existing accounts are up dramatically and the trends for patient testing are moving higher and at a faster pace than our original expectations.
- The Company is currently utilising the results from the recent Heart Failure trial to finalise the development of the SOZO Heart Failure application. The Company is very encouraged by the development of the application and the opportunity it presents. We expect to initiate Stage 1 of the commercialisation launch later this calendar year.

# **Regulatory and Clinical Highlights:**

- Announced the NCCN Clinical Practice Guidelines for Breast Cancer (NCCN Guidelines®) were updated with new recommendations for early detection and diagnosis of lymphoedema to achieve optimal management. Additionally, healthcare providers are now encouraged to consider pre-treatment baseline measurements for patients with lymphoedema risk factors. [Please refer to the ASX Announcement from 10 February 2020 for more details on the announcement.]
- Announced US FDA 510(k) Clearance for Protein Calorie Malnutrition Assessment.
   The new clearance enables ImpediMed to market SOZO for assessing patients at risk of protein calorie malnutrition (PCM).
- In addition, the clearance included the ability to track clinically relevant body composition parameters over time in healthy and unhealthy patient populations.
- The PREVENT Trial Paper evaluating the 2-year trial data for bioimpedance spectroscopy verses tape measure was submitted and is currently in the peer review process ahead of acceptance and publication.
- Meta-analysis manuscript evaluating bioimpedance spectroscopy, combining data across multiple studies, was submitted and awaits review and publication.
- Heart Failure (HF) manuscript using bioimpedance as a tool in the clinical assessment and treatment of HF patients is being finalised and is expected to be submitted for peer review and publication in the coming weeks.
- The submission to remove the contra-indication for the use of bioimpedance spectroscopy in Heart Failure patients with pacemakers has been finalised and is currently being evaluated by the US FDA.
- Independent studies continue to be submitted and published. One of the latest studies published in Cancers, A Preoperative Assessment of Upper Extremity Secondary Lymphoedema, submitted by The Department of Surgery, Memorial Sloan Kettering Cancer Center, evaluated the most commonly used preoperative assessment tools for patients undergoing surgical treatment for secondary upper extremity lymphoedema. The report stated that the "L-Dex® score was found to be the most rapid and reliable non-invasive method for detecting early-stage lymphedema in this study".

 Macquarie University, through its Australian Lymphoedema Education Research and Treatment (ALERT) team and Louise Koelmeyer, published a study comparing ImpediMed's SOZO and U400 devices. The findings support impedance measurements being made reliably using either the leaded or stand-on device representing supine and upright measurement positions respectively. This work is important as it provides peer-reviewed clinical evidence that studies which have been previously conducted on the U400 can be applied to SOZO.

"We are excited about the progress we've made building our business this half-year through the SOZO connected digital health platform. The release of several important publications, the commercial launch of our Heart Failure application and the continued expansion of our lymphoedema sales offering will further drive commercial expansion and adoption of the SOZO platform," said Richard Carreon, Managing Director and CEO of ImpediMed.

"We are also excited to have now reached the milestone of over 100,000 patient measurements since the launch of SOZO. The feedback from the clinicians is inspiring. Institutions who have implemented the Lymphoedema Prevention Program are already reporting significant reductions in lymphoedema rates," continued Mr Carreon. "Additionally, we are building a large dataset of human fluid levels which will be very valuable in providing new insights into the course and care of a large number of chronic disease states."

ImpediMed is using its dataset to improve its proprietary measurement algorithms and to secure new indications from the FDA. Earlier this year, SOZO became the first-ever medical device to pursue FDA clearance for Protein Calorie Malnutrition and the only bioimpedance spectroscopy device to secure FDA clearance for body composition parameters in unhealthy patients.

"With its new indications, SOZO is becoming a more complete solution for oncology customers," continued Mr Carreon. "In addition to facilitating early detection of lymphoedema, SOZO offers cancer patients and their care providers objective measures of overall health that can inform supportive care services."

#### **Contact Details**

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#### **About ImpediMed**

Founded and headquartered in Brisbane, Australia with US and European operations, ImpediMed is a medical software technology company that non-invasively measures, monitors and manages fluid status and tissue composition using bioimpedance spectroscopy (BIS).

ImpediMed produces a family of FDA cleared and CE Marked medical devices, including SOZO® for multiple indications including heart failure, protein calorie malnutrition and lymphoedema, sold in select markets globally.

For more information, visit <u>www.impedimed.com</u>.

## **Forward-Looking Statements**

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management.

All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to our ability to expand sales and market acceptance in the US and Australia including our estimates of potential revenues, costs, profitability and financial performance; our ability to develop and commercialise new products including our ability to obtain reimbursement for our products; our expectations with respect to our clinical trials, including enrolment in or completion of our clinical trials and our associated regulatory submissions and approvals; our expectations with respect to the integrity or capabilities of our intellectual property position.

Management believes that these forward-looking statements are reasonable as and when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. ImpediMed does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. ImpediMed may not actually achieve the plans, projections or expectations disclosed in forward-looking statements. Actual results, developments or events could differ materially from those disclosed in the forward-looking statements.

All FY'20 revenue and cash flow numbers are unaudited. CRP, ARR and TCV are non-AASB financial metrics that do not represent revenue in accordance with Australian Accounting Standards.

<sup>&</sup>lt;sup>1</sup> Contracted Revenue Pipeline (CRP): Future period revenue amounts related to TCV<sup>iii</sup> that are yet to be reported as recognised revenue.

<sup>&</sup>lt;sup>ii</sup> Annual Recurring Revenue (ARR): The amount of revenue reasonably expected to be booked for the next 12-month period based on existing signed contracts, and assuming installation upon sale.

Total Contract Value (TCV): Total value of customer contracts including one-time and recurring revenue.

ABN 65 089 705 144

# **Appendix 4D**

for the half-year ended 31 December 2019 (previous corresponding period : half-year ended 31 December 2018)

The information contained in this document should be read in conjunction with the financial statements for the year ended 30 June 2019 and any public announcements made by ImpediMed Limited and its controlled entities (the "Group") during the interim reporting period in accordance with continuous disclosure obligations arising under the Corporations Act 2001.

2	Results for announcement to the market			
		Current period	Increase / Decrease	Movement %
		\$000		
	2.1 Revenue from ordinary activities	2,837	Increase	56%
	2.2 Loss from ordinary activities after tax attributable to members	(12,941)	Increase	7%
	2.3 Net loss for the period attributable to members	(12,941)	Increase	5%
	2.4 Dividends	NIL		

There were no dividends declared and paid during the half year on ordinary shares. There were no dividends proposed and not yet recognised as a liability during the half year.

2.5 Dividend Record Date Not applicable

2.6 Explanation of operating performance

Refer to the Operating and Financial Review in the Directors' Report of the half-year Financial Report for the current reporting period.

During the current reporting period, the Group applied AASB 16 Leases for the first time. Refer to Note 16 for additional information.

3	Net tangible assets per ordinary security	Current period		Previous corresponding period		
	Net tangible assets (\$000)	\$	10,572	\$	22,271	
	Issued share capital at reporting date (\$000)	\$	232,746	\$	219,744	
	Number of shares on issue at reporting date		509,708,587		378,993,655	
	Net tangible assets per ordinary security	\$	0.02	\$	0.06	

#### Acquisitions and divestments

N/A

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#### 5 Details of dividends

There were no dividends paid during the period or payable at 31 December 2019.

#### 6 Dividend Reinvestment Plans

The Group has no dividend reinvestment plan.

## Associates and joint ventures

There are no equity accounted associates and joint venture entities.

#### Accounting standards

The Financial Report for the group has been prepared in accordance with Australian Equivalents to International Financial Reporting Standards.

#### 9 Auditors' review report

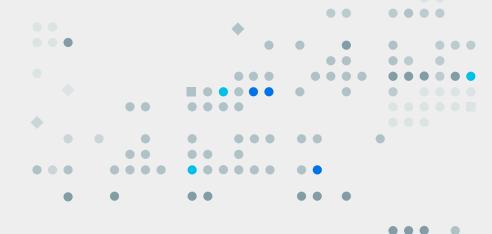
The review report prepared by the independent auditor Ernst & Young has been issued with an Emphasis of Matter paragraph regarding material uncertainty relating to Going Concern, and is provided with the half-year Financial Report.

# **Financial Report**

For the Half-Year Ended 31 December 2019



# Platform Technology. Transforming Care.



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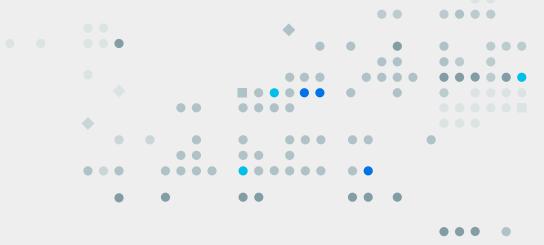
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# **Financial Report**

For the Half-Year Ended 31 December 2019

# Corporate Information

Chapter 1



# **Corporate Information**

This financial report covers the consolidated entity comprising ImpediMed Limited ("ImpediMed", the "Parent" or "Company") with its wholly owned subsidiaries (the "Group"). The Parent's functional and presentation currency and the Group's presentation currency is the Australian dollar (AUD or \$). Certain prior period amounts have been reclassified for consistency with the current period presentation.

A description of the Group's operations and of its principal activities is included in the operating and financial review in the Directors' Report. The Directors' Report is not part of the financial report.

# Directors

### **Non-Executive Directors**

S Ward, Chairman

J Downes

**G** Goetzke

R Graham

A Patel

**D** Williams

Managing Director

R Carreon, Managing Director and CEO

# Company Secretary

Ralph

### **Registered Office**

Unit 1, 50 Parker Court Pinkenba QLD 4008

#### **Principal Places of Business**

#### **US Headquarters**

5900 Pasteur Court, Suite 125 Carlsbad CA 92008 Phone: +1 760 585 2100

#### **AU Headquarters**

Unit 1, 50 Parker Court Pinkenba QLD 4008 Phone: +61 7 3860 3700

# Share Register

Link Market Services Level 21 10 Eagle Street Brisbane QLD 4000 Phone: +61 7 3320 2200

ImpediMed Limited shares are listed on the Australian Securities Exchange (ASX): ASX code "IPD".

#### Website

www.impedimed.com

#### **Solicitors**

Johnson Winter & Slattery Level 25, 20 Bond Street Sydney NSW 2000

Sheppard Mullin Richter & Hampton LLP 12275 El Camino Real Suite 200 San Diego CA 92130 USA

## Bankers

Commonwealth Bank of Australia 240 Queen Street Brisbane QLD 4000

Bank of America 701 B Street Suite 2300 San Diego CA 92101 USA

# **Auditors**

Ernst & Young Level 51, 111 Eagle Street Brisbane QLD 4000

# Remuneration Advisors to the Board of Directors

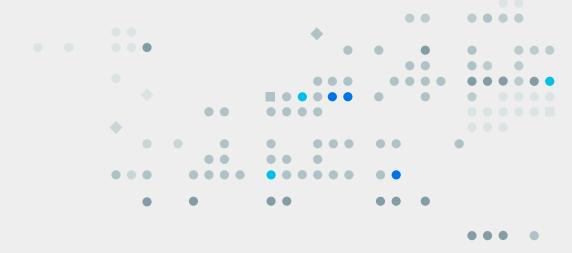
Willis Towers Watson 300 S. Grand Avenue Los Angeles CA 90071 US

# **Financial Report**

For the Half-Year Ended 31 December 2019

# Directors' Report

Chapter 2





Your Directors submit their report together with the consolidated interim financial report for ImpediMed Limited for the half-year ended 31 December 2019.

# **Directors**

The names and details of the Parent's Directors (the "Board") in office during the half-year and until the date of this report are outlined below. Directors were in office for this entire period unless otherwise stated.



Scott Ward
MS, BSc
Opn-Executive Chairman



Judith Downes
BA(Hons), DipEd,
GradDipBus(Acct), FAICD,
FCPA, FCA
Non-Executive Director



Gary Goetzke
Juris Doctorate
Non-Executive Director



Robert Graham
AO, FAA, FAHMS, MBBS, MD,
FRACP, FACP, FAHA, GAICD
Non-Executive Director



Amit Patel
MBA, BME
Non-Executive Director



**Donald Williams**BAcy, CPA
Non-Executive Director

# MANAGING DIRECTOR



Richard Carreon
Executive Director

# **Principal Activities**

ImpediMed is a medical software technology company that non-invasively measures, monitors and manages fluid status and tissue composition using bioimpedance spectroscopy (BIS).

ImpediMed produces a family of FDA cleared and CE Marked medical devices, including SOZO® for multiple indications including heart failure and lymphoedema. ImpediMed's devices are sold in select markets globally.

The principal activities of the Group during the period were the development, manufacture and sale of bioimpedance spectroscopy devices and software services with a focus on the early detection of lymphoedema and monitoring heart failure patients.

# **Group Overview**

ImpediMed Limited was founded in Brisbane, Australia in September 1999, and was listed on the ASX on 24 October 2007. The Group consists of four entities:

ImpediMed Limited, the Parent company operating in medical markets in regions outside North America; incorporated in 1999 and listed on the ASX on 24 October 2007.

**ImpediMed Incorporated**, a Delaware corporation in medical markets in North America.

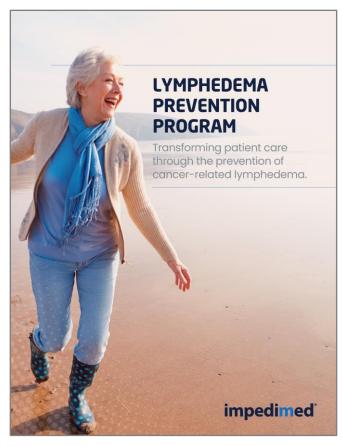
**impediMed Hellas**, a Kalamaria, Greece corporation in a research & development and marketing capacity in Europe.

ImpediMed TM Incorporated (formerly XiTRON Technologies, Incorporated), a California corporation formerly operating in power test and measurement markets globally. ImpediMed TM Incorporated discontinued operations during the year ended 30 June 2019.

For more information on ImpediMed and the Lymphoedema Prevention Program, please visit:

www.impedimed.com

www.preventlymphedema.com





# **Milestones**

# October 2019

# ImpediMed Announces Program to End Cancer-Related Lymphoedema

The Company launched the Lymphoedema Prevention Program, a comprehensive program that utilises ImpediMed's Test, Trigger, Treat™ protocol for early detection and intervention of cancer-related lymphoedema.

The program has a goal of ending cancer-related lymphoedema. ImpediMed's new website, www.preventlymphedema.com, is designed to highlight improvements in the early detection of lymphoedema.

Routine lymphoedema testing of cancer survivors uses the company's FDA-cleared SOZO device with BIS (L-Dex®) technology, which measures extracellular fluid. A significant increase in a patient's L-Dex score is a trigger to evaluate the patient and initiate intervention.

# November 2019

# US FDA 510(k) Clearance for Protein Calorie Malnutrition Assessment

The new clearance enables ImpediMed to market SOZO for assessing patients at risk of protein calorie malnutrition (PCM) and to track clinically relevant body composition parameters over time in healthy and unhealthy patient populations. Specifically, the claims around PCM are to aid clinicians who are using Subjective Global Assessment (SGA) tools to assess patients at risk of PCM.

SGA Tools such as the American Society of Parenteral and Enteral Nutrition (A.S.P.E.N) guidelines define changes in physical attributes as assessment criteria for PCM in patients. Weight, muscle mass, fat mass and oedema are tracked and reported by SOZO and can be used by clinicians to support their assessment and diagnosis of PCM.

SOZO is the first medical device to receive FDA clearance for this indication. Today, Protein Calorie Malnutrition is not easily diagnosed, and if it is, it's normally in the late stages which makes it difficult and expensive to treat. Patients undergoing cancer treatment are especially prone to developing PCM. SOZO offers an objective way to measure several key body parameters that provide an objective assessment to clinicians.

FDA clearance for body composition measurements in an unhealthy patient population. Obtaining this clearance is significant. All other bioimpedance devices for body composition are only able to be used in a healthy patient population. This is one more clinical distinction for our technology and will force potential competitors to show clinical evidence they can accurately measure body composition in unhealthy patients.

# **November 2019**

# **Compelling Heart Failure Data**

ImpediMed's Heart Failure (HF) Advisory Board met at the 2019 Heart Failure Society of America (HFSA) Scientific Meeting. Following this meeting, ImpediMed used its growing patient database to provide a baseline for development of a HF index and developed reference ranges for monitoring patients living with heart failure. These advancements, combined with the information obtained from the initial HF study, are allowing ImpediMed to develop an application that both identifies and tracks fluid overload in HF patients.

The Heart Failure manuscript using bioimpedance as a tool in the clinical assessment and treatment of HF patients is being finalised and is expected to be submitted for peer review and publication in the coming months

The submission to remove the contra-indication for the use of bioimpedance spectroscopy in Heart Failure patients with pacemakers has been finalised and is currently being evaluated by the FDA.

## December 2019

# **PREVENT Trial 2-Year Data Submitted**

The PREVENT Trial Paper evaluating the 2-year data for bioimpedance spectroscopy verses tape measure was submitted and is currently in the peer review process ahead of acceptance and publication.

# December 2019

## **Meta-Analysis**

Meta-analysis manuscript evaluating bioimpedance spectroscopy, combining data across multiple studies, was submitted and awaits review and publication. This manuscript evaluated 50 studies comprising more than 17,000 patients.

# **Financial Report**

For the Half-Year Ended 31 December 2019







# SOZO® Digital Health Platform

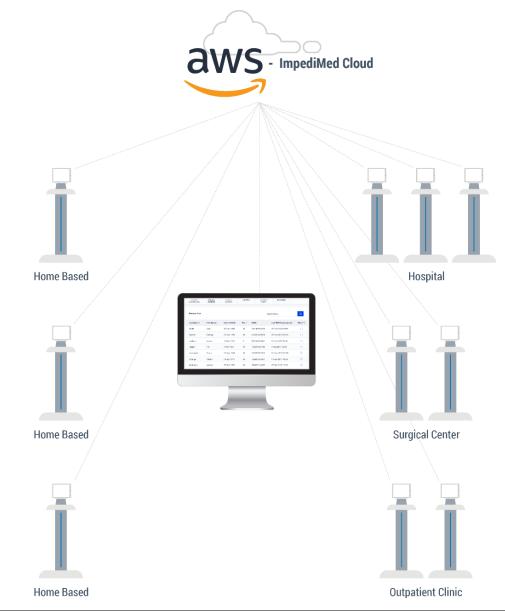
SOZO, the world's most advanced, non-invasive bioimpedance spectroscopy (BIS) device, incorporates ImpediMed's technology to aid in the assessment of secondary lymphoedema, as well as to monitor patients living with heart failure. SOZO delivers a precise snapshot of L-Dex®, fluid status, and tissue composition in less than 30 seconds, allowing clinicians across multiple specialties to provide individualised, proactive care that can help improve patient outcomes.

# **Connected Digital Health Platform**

**SOZO – Connected Digital Health Platform** 

SOZO is a highly disruptive technology offering a highly scalable business model. SOZO provides a cloud-based software solution to hospital systems, clinicians and patients that allows access to comprehensive patient data and digital health-information across the care continuum. With seamless integration into hospitals, clinical and home settings, the technology platform allows for ease of management of large patient populations.

Our software indications are all interwoven to increase the clinical utility of our technology in patient care systems. Our ability to easily and inexpensively obtain clearances for new, critical indications drives adoption and expands our footprint in leading centers. It also drives adoption across multiple medical specialties and, combined, these establish significant barriers to competitive entry.



# Connected Digital Health Platform

Comprehensive patient data

Access to information across the care continuum

Manage large patient populations

Integrates seamlessly into hospital, clinical, and home settings

Growing database of patient measurements

## Data is already driving

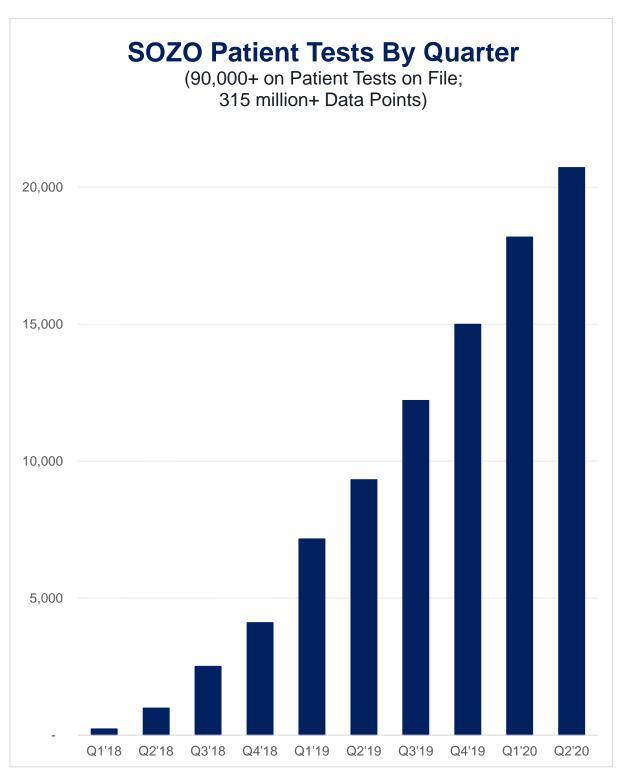
- Increased accuracy
- Automated protocols
- Real world clinical data to support FDA filings

# **Technology Adoption**

# **SOZO Patient Tests**

As of 31 December 2019, ImpediMed's customers have conducted more than 90,000 patient tests, with almost 21,000 completed in Q2 FY'20 alone. This is an increase of more than 15% quarter over quarter since the launch of SOZO. To date, our growing patient database now has more than 315 million individual data points that have allowed us to:

- Increase the accuracy of SOZOs
- Automate key protocols
- Improve our current algorithms
- · Create new algorithms, and
- Provide real-world data to the FDA for regulatory clearances



# **Operating and Financial Review**

# **Operating Results for the Half-Year**

# Revenue and SaaS Financial Metrics

SOZO Revenue for the current period was \$2.1 million (31 December 2018: \$0.8 million), an increase of 163% over the previous corresponding period. This increase in revenue was attributable to SOZO commercialisation efforts in the US and included both the upfront SOZO device revenue and the recurring subscription revenue streams.

Of the SOZO revenue, \$1.6 million related to recurring subscription revenue streams (31 December 2018: \$0.5 million), a 220% increase over the previous corresponding period.

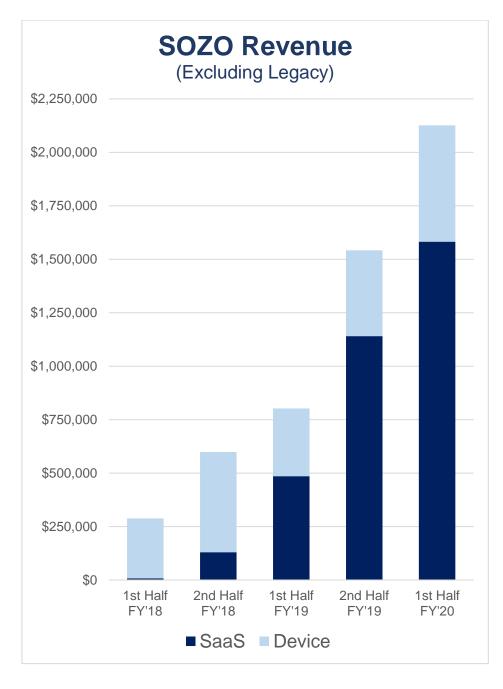
Total Revenue for the current period was \$2.8 million (31 December 2018: \$1.8 million), an increase of over 56% from the previous corresponding period. The increase in revenue was attributable to SOZO, as mentioned above, but was offset by a decrease in

legacy consumables revenue as the existing customer base continued to transition to the SOZO platform.

As of 31 December 2019, there were more than 480 SOZO units in the market (31 December 2018: 317 SOZO units), representing a 51% increase in the number of units in the market year-over-year.

In addition to revenue recognised during the current period, the Contracted Revenue Pipeline (CRP) at 31 December 2019 totaled \$9.6 million (31 December 2018: \$7.0 million), an increase of 37% over the previous corresponding period.

Annual Recurring Revenue (ARR) at 31 December 2019 totaled \$4.2 million (31 December 2018: \$2.5 million), an increase of 68% over the previous corresponding period.





90,000+ Patient Tests on file



Churn Rate less than 0.5%



· 480+ Devices Sold to date



100% Renewal Rate

# Operating Results – Investing in Large, Growing Markets

Net loss from continuing operations for the period was \$12.9 million (31 December 2018: \$12.1 million). The increased loss from continuing operations, when compared with the prior period, is primarily attributed to expenditure on the following key initiatives:

- (a) expanding reimbursement in the US market (engaged MCRA, one of the leaders in US reimbursement, increasing the resources to drive payment of our unique CPT® I Code (93702));
- (b) expanding sales and marketing efforts in the US market (through the launch of the Lymphoedema Prevention Program and the corresponding hiring of US sales and marketing personnel);
- (c) software enhancements (launching SOZO software v3.0.1 and other critical software initiatives); and
- (d) investment in clinical data (PREVENT trial, Meta-Analysis, and Heart Failure reference ranges and manuscript).

Cost of goods sold for the current period were \$0.7 million (31 December 2018 \$0.7 million). There was a decrease in device costs in the current period, which was offset by an increase in costs associated with

subscription services attributable to a larger SOZO customer base.

Gross margin percentage for the Group was 74% for the current period (2018: 63%). Gross margins increased in the current period due to an increase in recurring revenue under the subscription-based contracts.

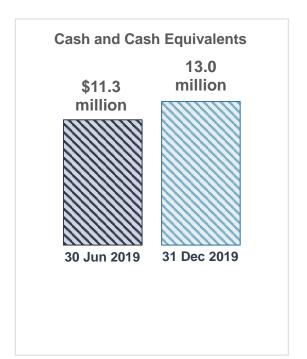
Salaries and benefits for the period ended 31 December 2019 totaled \$7.7 million (31 December 2018 \$7.7 million). Salaries remained consistent period over period as the increased expense for sales and marketing personnel were predominantly offset by the reduction to expenses from certain executives participating in the Executive Share Plan. Refer to Note 7 of the Financial Statements for additional information.

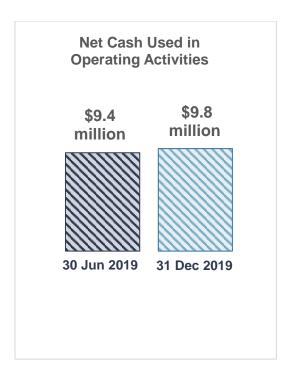
Share-based payments for the period ended 31 December 2019 totaled \$2.0 million (31 December 2018 \$1.9 million), an increase of 5%. This increase is primarily related to Executives and Directors participating in the Executive and Non-Executive Share Plans. Refer to Note 12 of the Financial Statements for additional information.

Refer to Note 7 of the Financial Statements for additional information on all other significant movements in operating expenses and how they relate to our key initiatives.

Glossary of Financial Terms used by ImpediMed							
Medical Revenue	The total revenue recognised during a given period related to the medical segment.						
Total Contract Value (TCV) (i)	The total value of customer contracts including one-time and recurring revenue.						
Contracted Revenue Pipeline (CRP) (i)	The future period revenue amounts related to TCV that are yet to be reported as recognised revenue. Certain customer contracts that make up the Group's CRP contain cancelation clauses related to services yet to be performed. The Contracted Revenue Pipeline assumes no churn, highlighting the importance of customer experience and satisfaction.						
Annual Recurring Revenue (ARR) (i)	The amount of revenue reasonably expected to be booked for the next 12-month period based on existing contracts, and assuming installation upon sale.						

TCV, CRP and ARR are unaudited, non-AASB financial metrics that do not represent revenue in accordance with Australian Accounting Standards.





# Review of Financial Condition – Liquidity and Capital Resources

Cash and cash equivalents were \$13.0 million at 31 December 2019 (30 June 2019: \$11.3 million). Net cash used in operating activities for the period ended 31 December 2019 was \$9.7 million (31 December 2019 \$9.4 million). The increase in operating cash outflow was primarily attributable to the expenditure on the key initiatives outlined in the Operating Results above.

Cash outflow from investing activities was \$1.1 million during the period (31 December 2018: \$0.5 million). The increase in cash flows used in investing activities is primarily related to software enhancements associated with the capitalisation of software development costs.

Cash inflow from financing activities was \$12.6 million during the period (31 December 2018: \$0.01 million). The following outlines the movements in financing activities during the period:

- \$12.8 million cash inflow, net of transaction costs, through the issue of 126,602,928 ordinary shares related to the Entitlement Offer completed on 16 July 2019.
  - \$0.1 million cash inflow, net of transaction costs, from July 2019 December 2019 through the issue of 3,301,672 ordinary shares stemming from employees exercising options and performance rights, as well as shares issued under the Executive and Non-Executive Share Plans.
- \$0.2 million cash outflow, from the payment of lease liabilities under AASB 16 *Leases*.

# Foreign Currency – Effects on Operating Results

The Group maintains a significant portion of available funds in U.S. dollars to match U.S. dollar expenditure needs. The loss from continuing operations for the period before income tax includes a realised foreign exchange loss arising from operating expenses in the U.S and Europe.

The spot exchange rate for the beginning and end of the current reporting period was AUD \$1.00 to USD \$0.70 for both periods. The spot exchange rate for the beginning and end of the prior reporting period was AUD \$1.00 to USD \$0.74 and USD \$0.71, respectively. This fluctuation of the exchange rate led to an unfavourable outcome in reporting operating expenditure but led to a favourable outcome in reporting cash and cash equivalents when compared to the prior period.

The average exchange rate for the reporting period was \$0.68 (Australian dollar (AUD) to US dollar (USD)) (2018: \$0.72). During 2019, the Group incurred unrealised mark-to-market foreign currency translation losses of less than \$0.2 million (2018: \$0.1 million). The loss in both periods primarily relates to exchange rate fluctuations in foreign denominated trade receivables and payables between the transaction date and settlement date.

# Significant Events after the Balance Sheet Date

# January 2020

# Independent Studies Continue to be Submitted and Released

An independent paper was published in Cancers, titled *A Preoperative Assessment of Upper Extremity Secondary Lymphoedema*. The paper, which was submitted by The Department of Surgery, Memorial Sloan Kettering Cancer Center, evaluated the most commonly used preoperative assessment tools for patients undergoing surgical treatment for secondary upper extremity lymphoedema. The report stated that the "L-Dex® score was found to be the most rapid and reliable non-invasive method for detecting early-stage lymphedema in this study".

# February 2020

# NCCN Guidelines® for Breast Cancer Updated for Lymphoedema

The NCCN Clinical Practice Guidelines for Breast Cancer (NCCN Guidelines®) were updated with new recommendations for early detection and diagnosis of lymphoedema to achieve optimal management. Additionally, healthcare providers are now encouraged to consider pretreatment baseline measurements for patients with lymphoedema risk factors.

The NCCN Guidelines® update follows a request by Vanderbilt University School of Nursing, Lymphedema Education and Research Network (LE&RN), and the American Society of Breast Surgeons Foundation to language recommending establishing surveillance program with BIS to detect subclinical breast cancer-related lymphoedema (BCRL) and initiate early intervention to reduce the need for complete decongestive physiotherapy. pretreatment recommendation for measurements to facilitate the earliest identification of subclinical lymphoedema was also requested.

The National Comprehensive Care Network® (NCCN®) documents recommendations for diagnostic, treatment, and supportive services provided to cancer patients. The NCCN Guidelines® are referenced by providers and payors when making decisions about care and coverage of oncology patient services. While the recent updates do not specify a measurement technique, they are consistent with the Test, Trigger, Treat™ protocol outlined in ImpediMed's Lymphoedema Prevention Program (LPP), which is supported by evidence from the PREVENT Trial.

# February 2020

# Further Validation of SOZO by Macquarie University

Macquarie University, through its Australian Lymphoedema Education Research and Treatment (ALERT) team and Louise Koelmeyer, published a

study comparing ImpediMed's SOZO and U400 devices. In the study, 100 women were assessed using both devices. SOZO measurements were taken in standing and seated positions while the U400 measurements were taken in standing, seated and supine positions.

The results from the study demonstrated that the L-Dex scores were highly correlated ( $r_c = 0.925$ ). They found that L-Dex measurements could be made reliably but not interchangeably with either device. There was as expected absolute difference between the SOZO standing and U400 supine due to the differences in electrode position.

The findings support impedance measurements being made reliably using either the leaded or stand-on device representing supine and upright measurement positions respectively. This work is important as it provides peer-reviewed clinical evidence that studies which have been previously conducted on the U400 can be applied to SOZO.

# **Corporate Governance**

On 27 March 2014, the ASX Corporate Governance Council (CGC) released the third edition of their corporate governance principles and recommendations, including ASX listing rule 4.10.3.

Details of ImpediMed's corporate governance policies and procedures, including information about Board Committees and Corporate Charters can be found on the Group's website under the Investors section:

https://www.impedimed.com/about/investors/corporate-governance/

# **Rounding of Amounts**

The amounts contained in this report and in the financial report have been rounded to the nearest \$1,000 (where rounding is applicable and where noted (\$000) under the option available to ASIC Corporations (Rounding in Financial/Directors' Reports) Instruments 2016/191. The Group is an entity to which the Class Order applies.

# Auditor's Independence Declaration and Non-Audit Services

The Directors append to the Directors' Report to the following declaration from our auditors, Ernst & Young.

Signed in accordance with a resolution of the Directors.

Scott Ward Chairman Judith Downes Director

20 February 2020



Ernst & Young 111 Eagle Street Brisbane QLD 4000 Australia GPO Box 7878 Brisbane QLD 4001 Tel: +61 7 3011 3333 Fax: +61 7 3011 3100

ey.com/au

# Auditor's Independence Declaration to the Directors of ImpediMed Limited

As lead auditor for the review of ImpediMed Limited for the half-year ended 31 December 2019, I declare to the best of my knowledge and belief, there have been:

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

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

Ernst & Young

Ernst & Young

Jennifer Barker Partner

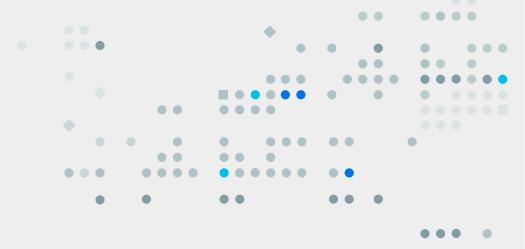
20 February 2020

# **Financial Report**

For the Half-Year Ended 31 December 2019

# Financial Statements

Chapter 3





# **CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME**

For the Half-Year Ended 31 December

	Notes	2019 \$000	2018 \$000
Continuing Operations			
SOZO Revenue	4	2,126	803
Legacy Revenue	4	687	969
Other Revenue	4	24	29
Total Revenue from Contracts with Customers		2,837	1,801
Cost of Goods Sold		(735)	(670)
Gross Profit		2,102	1,131
Other Income	6	1,493	1,371
Finance Income, net	6	39	220
Salaries and Benefits	7	(7,715)	(7,664)
Share-based Payments	12	(1,999)	(1,861)
Research and Clinical Trials	7	(1,974)	(1,454)
Administrative and Governance Fees	7	(1,383)	(1,120)
Consulting and Professional Fees	7	(1,324)	(1,008)
Other Expenses	7	(2,171)	(1,753)
Loss from Continuing Operations Before Income Tax		(12,932)	(12,138)
Income Tax		(9)	(6)
Loss from Continuing Operations		(12,941)	(12,144)
Loss from Discontinued Operations	17	-	(127)
Net Loss		(12,941)	(12,271)
Other Comprehensive Income			
Items that may be reclassified as profit:			
Foreign Currency Translation Gain		71	1,292
Other Comprehensive Gain for the Period, Net of		71	1,292
Total Comprehensive Loss		(12,870)	(10,979)
		\$	\$
Basic and Diluted Loss per Share	2	(0.03)	(0.03)
The above Consolidated Statement of Comprehensive Income shortes.	nould be read ir	n conjunction with th	e accompanyir

# **CONSOLIDATED BALANCE SHEET**

		Notes	As at 31 Dec 2019 \$000	As at 30 Jun 2019 \$000
	Assets			
	Current Assets			
	Cash and Cash Equivalents	8	12,971	11,330
	rade and Other Receivables	9	2,376	3,488
	Contract Assets		610	497
	Inventories		745	1,121
	Prepayments and Other		422	537
	<b>Total Current Assets</b>		17,124	16,973
	Non-Current Assets			
	Other Financial Assets		503	45
	Right of Use Asset	16	782	-
	Property and Equipment		225	188
	Intangible Assets	10	6,002	5,375
	<b>Total Non-Current Assets</b>		7,512	5,608
	otal Assets		24,636	22,581
7(2)				
	Liabilities			
	Current Liabilities			
	Trade and Other Payables		3,108	2,447
	Contract Liabilities		485	520
	Lease Liabilities	16	298	-
	Provisions		2,191	3,694
	Total Current Liabilities		6,082	6,661
	Non-Current Liabilities			
	Lease Liabilities	16	535	-
	Provisions		53	135
~	Total Non-Current Liabilities		588	135
	Total Liabilities		6,670	6,796
	Net Assets		17,966	15,785
	Equity			
	Issued Capital	11	232,746	219,727
	Reserves		26,845	24,775
	Accumulated Losses		(241,625)	(228,717)
	Total Equity		17,966	15,785

The above Consolidated Balance Sheet should be read in conjunction with the accompanying notes.

# **CONSOLIDATED STATEMENT OF CASH FLOWS**

For the Half-Year Ended 31 December

	Notes	2019 \$000	2018 \$000
Cash Flows from Operating Activities			
Receipts from Customers (Inclusive of GST and US Sales Tax)		2,694	2,295
Payments to Suppliers (Inclusive of GST and US Sales Tax)		(5,850)	(5,993)
Payments to Employees		(9,343)	(8,858)
Interest Received		77	227
Other Receipts		2,650	2,949
Net Cash Flows Used in Operating Activities		(9,772)	(9,380)
Cash Flow from Investing Activities			
Proceeds from the Disposal of Assets, Net of Disposal Costs		-	467
Purchase of Property and Equipment		(91)	(21)
Development Expenditures and Purchase of Intangibles		(1,040)	(974)
Net Cash Flows Used in Investing Activities		(1,131)	(528)
Cash Flows from Financing Activities			
Proceeds from Issue of Ordinary Shares	11	13,929	16
Transaction Costs from Capital Raising	11	(1,103)	(2)
Payment of Lease Liabilities		(208)	-
Net Cash Flows from Financing Activities		12,618	14
Net Increase/(Decrease) in Cash and Cash Equivalents		1,715	(9,894)
Net Foreign Exchange Differences		(74)	1,187
Cash and Cash Equivalents at Beginning of Period		11,330	31,345
Cash and Cash Equivalents at End of Period	8	12,971	22,638

The above Consolidated Statement of Cash Flows should be read in conjunction with the accompanying notes.

# **CONSOLIDATED STATEMENT OF CHANGES IN EQUITY**

		Notes	Issued Capital \$000	Share Reserves \$000	Foreign Currency Reserves \$000	Reserves \$000	Accumulated Losses \$000	Total \$000
At 1 Ju	ıly 2018		219,746	16,022	4,630	20,652	(204,594)	35,804
	r the Period from uing Operations		-	-	-	-	(12,144)	(12,144)
	om the Period from tinued Operations		-	-	-	-	(127)	(127)
	Comprehensive Gain from uing Operations		-	-	1,506	1,506	-	1,506
	Comprehensive Loss from tinued Operations		-	-	(214)	(214)	-	(214)
Total C the Per	omprehensive Loss for iod		-	-	1,292	1,292	(12,271)	(10,979)
Share	Transactions: e-based Payments of Capital Raising	12	(2)	1,861 -	-	1,861 -	-	1,861 (2)
At 31 [	December 2018		219,744	17,883	5,922	23,805	(216,865)	26,684
At 1 Ju	ıly 2019		219,727	18,871	5,904	24,775	(228,717)	15,785
	of Adoption of AASB 16	16	-	-	-	-	33	33
At 1 Ju	lly 2019 (adjusted)		219,727	18,871	5,904	24,775	(228,684)	15,818
1 /	r the Period from uing Operations		-	-	-	-	(12,941)	(12,941)
	Comprehensive Gain from uing Operations		-	-	71	71	-	71
Total C the Per	omprehensive Loss for iod		-	-	71	71	(12,941)	(12,870)
Share	Transactions: e-based Payments nent of Ordinary Shares s of Capital Raising	12 11 11	- 14,011 (992)	1,999 - -	-	1,999 - -		1,999 14,011 (992)
7 5500	December 2019		232,746	20,870	5,975	26,845	(241,625)	17,966

# **NOTES TO THE FINANCIAL STATEMENTS**

FOR THE HALF-YEAR ENDED 31 DECEMBER 2019

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# 1. Basis of Preparation

## **Corporate Information**

The consolidated financial statements of ImpediMed Limited for the six-months ended 31 December 2019 were authorised for issue in accordance with a resolution of the Board of Directors on 20 February 2020.

ImpediMed Limited is a for profit company limited by shares incorporated in Australia whose shares are publicly traded on the Australian Stock Exchange. The nature of the operations and principal activities of the Group are described in the Directors' Report.

#### Basis of Preparation

The interim consolidated financial statements ("financial report") for the half-year ended 31 December 2019 have been prepared in accordance with AASB 134 *Interim Financial Reporting* and the Corporations Act 2001.

The half-year financial report does not include all notes of the type normally included within the annual financial report and therefore cannot be expected to provide as full an understanding of the financial performance, financial position and financing and investing activities of the consolidated entity as the full annual financial report.

It is recommended that the half-year financial report be read in conjunction with the annual report for the year ended 30 June 2019 and considered together with any public announcements made by the Group during the half-year ended 31 December 2019 in accordance with the continuous disclosure obligations of the ASX listing rules.

The accounting policies and methods of computation are the same as those adopted in the most recent annual financial report with the exception of the impact of the adoption of new standards (refer to Note 16).

#### Reclassification

Certain prior period amounts have been reclassified for financial statement presentation purposes. These reclassifications have no impact to previously reported net loss and other comprehensive income.

#### Going Concern

These financial statements have been prepared on the going concern basis, which assumes continuity of normal business activities, the realisation of assets and the settlement of liabilities in the ordinary course of business. The Group had cash of \$13.0 million at 31 December 2019 (30 June 2019: \$11.3 million) and no borrowing from banks or other financial institutions at that date. The Group incurred a net loss of \$12.9 million for the half-year ended 31 December 2019 (31 December 2018: \$12.3 million) and had \$9.8 million (31 December 2018: \$9.4 million) of cash outflows from operations.

Whilst the Group continues to generate operating losses and net cash outflows from operations, the Group's future viability is dependent on (i) cash inflows from growth in future sales, (ii) capital raises, or (iii) other funding arrangements.

The Directors believe that the Group has been successful in building a long-term business founded on strong technology. The Group is operating within large, growing markets and has seen positive traction in its initial revenue growth.

If the Group is unable to manage cash inflows and outflows at amounts as necessary to meet future operating plans, there is material uncertainty whether the Group will be able to continue as a going concern. The Directors are confident they will be able to generate cash flows that will provide sufficient funding to enable the Group to continue to be able to pay its debts as and when they fall due for a period in excess of 12-months from the date the financial report has been signed.

On that basis, the going concern basis of accounting has been used. No adjustment has been made to the amounts and classification of recorded assets and liabilities that might be necessary should the Group not continue as a going concern.

## Compliance with IFRS

The financial report complies with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board.

# 2. Earnings per Share (EPS)

The following reflects the net loss attributable to ordinary equity holders and the weighted average

number of ordinary shares used in the calculations of basic earnings per share:

	31 Dec 2019 \$000	31 Dec 2018 \$000
Net Loss Used in Calculating Basic and Diluted Earnings Continuing Operations Discontinued Operations	(12,941)	(12,144) (127)
Net Loss Attributable to Ordinary Equity Holders of the Parent for Basic and Diluted Earnings per Share	(12,941)	(12,271)
	No.	No.
Weighted Average Number of Ordinary Shares Used in Calculating  Basic and Diluted Earnings per Share	491,683,783	378,993,655
	\$	\$
Basic and Diluted Loss per Share	(0.03)	(0.03)
Basic and Diluted Loss per Share from Continuing Operations	(0.03)	(0.03)

Diluted EPS is calculated by taking the net loss attributable to ordinary equity holders and dividing it by the sum of the weighted average number of ordinary shares and the weighted average number of convertible instruments. For the financial half-year ended 31 December 2019, diluted EPS is equal to basic EPS as the Group is currently in a loss position and any conversion of instruments to ordinary shares would have an antidilutive effect on earnings per share.

As of the end of the current period there were 36,541,054 (31 December 2018: 32,830,038) options and 8,987,175 (31 December 2018: 4,741,500) performance rights on issue.

Basic earnings per share is calculated as net profit attributable to members of the Parent, adjusted to exclude any costs of servicing equity (other than dividends) and preference share dividends, divided by the weighted average number of ordinary shares, adjusted for any bonus element. Diluted earnings per share, which is currently not applicable to the Group due to the net loss, would be calculated as net profit attributable to members of the parent, adjusted for:

- Costs of servicing equity (other than dividends) and preference share dividends;
- The after-tax effect of dividends and interest associated with dilutive potential ordinary shares that have been recognised as expenses;
- Other non-discretionary changes in revenues or expenses during the period that would result from the dilution of potential ordinary shares;
- Divided by the weighted average number of ordinary shares and dilutive potential ordinary shares, adjusted for any bonus element.

## 3. Dividends Paid and Proposed

There were no dividends paid or proposed during the current period or in the prior period.

## 4. Segment Reporting

#### **Operating Segments**

Identification of Reportable Segments

The Group has identified its operating segments based on the internal reports that are reviewed and used by the Chief Executive Officer (whom is the Chief Operating Decision Maker) in assessing performance and in determining the allocation of resources.

The operating segments are identified by management according to the nature of the products and services provided, as the Group's risks and returns are affected predominantly by differences in the products produced and services provided. Discrete financial information about each of these operating businesses is reported to the Chief Executive Officer on at least a monthly basis.

During the half-year, the Chief Executive Officer reviewed the business revenue information categorised by the Group's SOZO and Legacy product lines which make up the Medical segment, consistent with the previous annual report.

# **Inter-Company Transactions**

Inter-company transactions are eliminated for the purposes of segment reporting.

## **Medical Segment**

The Medical segment is a supplier of non-invasive medical equipment of software emploving bioimpedance spectroscopy (BIS) technologies for use in the non-invasive clinical assessment and monitoring of tissue composition and fluid status. The Medical cash generating unit is the core business of the Group and is the main strategic operating segment. On a monthly basis, the Chief Executive Officer assesses the performance of the Medical segment by analysing the segment's revenue based on the SOZO product line and legacy product lines. The primary focus during the current period for the Medical segment was continuing the launch of SOZO and the introduction of the subscription revenue model, focused on building a high margin contracted revenue pipeline for strong recurring revenue growth. Refer to the 2019 Annual Report for additional information on the Group's segment reporting.

The following table presents revenue and profit information for reportable segments for the half-years ended 31 December 2019 and 2018:

Half-year Ended 31 December 2019 Medical			
Segment Revenue	SOZO <sup>®</sup>	Legacy	Total
	\$000	\$000	\$000
Revenue from Subscriptions and Consumables	1,582	503	2,085
Revenue from Devices	544	184	728
Total Revenue by Segment	2,126	687	2,813
Other Revenue			24
Total Revenue			2,837

Half-year Ended 31 December 2018	Medical		
Segment Revenue	SOZO®	Legacy	Total
	\$000	\$000	\$000
Revenue from Subscriptions and Consumables	486	846	1,332
Revenue from Devices	317	123	440
Total Revenue by Segment	803	969	1,772
Other Revenue			29
Total Revenue			1,801

## **Geographical Segments**

The following tables present revenue and profit/(loss) information and certain asset and liability information regarding geographical segments for the half-years ended 31 December 2019 and 2018. Revenue data is based on the location of the customer for geographical reporting purposes.

#### North America

The Group's North American office in Carlsbad, California serves as the operational hub for the Medical segment and the domicile of its main assets and executive personnel. This office sells and ships Medical segment products to customers located in the US.

#### Australia / Rest of World (ROW)

Australia is the corporate home office of the Group and the main domicile of its research and product development activities, contract manufacturing of devices and corporate services. The Australia / ROW geographical segment primarily sells and ships Medical segment products to customers and distributors located in Australia, Europe and the rest of the world excluding the US.

#### Geographical Segment Revenue

Half-year Ended 31 December 2019	North America \$000	Australia/ROW \$000	Total \$000
Revenue from Subscriptions and Consumables	1,881	204	2,085
Revenue from Devices	467	261	728
Other Revenues	16	8	24
Total Revenue from Contracts with Customers	2,364	473	2,837

Half-year Ended 31 December 2018	North America \$000	Australia/ROW \$000	Total \$000
Revenue from Subscriptions and Consumables	1,174	158	1,332
Revenue from Devices	298	142	440
Other Revenues	18	11	29
Total Revenue from Contracts with Customers	1,490	311	1,801

#### Sales of Goods - Device and Consumable Revenue

All segment assets relating to the Group's operating segments as at 31 December 2019 are Medical.

# 5. Revenue from Contracts with Customers

Revenue from contracts with customers is recognised when control of the goods or services are transferred to the customer at an amount that reflects the consideration to which the Group expects to be entitled in exchange for those goods or services. Refer to Note 4 for a breakdown of revenue by operating and geographical segments.

# 6. Finance and Other Income

Other Income	31 Dec 2019	31 Dec 2018
	\$000	\$000
R&D Tax Incentive (i)	1,493	1,345
Proceeds from Tax Refunds, Grants, and Other	-	26
Total Other Income	1,493	1,371

The Group receives payments for research & development (R&D) tax credits under the AusIndustry R&D Tax Incentive program. The Group accrues for amounts when there is reasonable assurance of receipt. Whilst there is a judgment involved in when there is reasonable assurance, the Group has a history of successful lodgings and receipts with the Australian Tax Office.

Finance Income	31 Dec 2019 \$000	31 Dec 2018 \$000
Interest Income – term deposits	76	220
Interest Expense – lease liability (i)	(37)	
Total Finance Income	39	220
Refer to Note 16 for details related to the implementation of AASB 16 Lease	S.	
7. Expenses	s.	
	31 Dec 2019 \$000	31 Dec 2018 \$000
7. Expenses	31 Dec 2019	\$000
7. Expenses Salaries and Benefits	31 Dec 2019 \$000	

# **Expenses**

Salaries and Benefits	31 Dec 2019 \$000	31 Dec 2018 \$000
Wages and Salaries (i) (ii)	5,682	5,401
Short-term Incentives and Sales Commissions	1,908	2,086
Superannuation	219	233
Employee Benefits and other costs	790	822
Capitalised Employee Costs (ii)	(884)	(878)
Total Salaries and Benefits	7,715	7,664

Total Salaries and Benefits	7,715	7,664
(i) The increase in Wages and Salaries primarily relates to the hiring of sales and mark Lymphoedema Prevention Program roll-out. This increase was partially offset by a certain executives as part of the Executive Share Plan. Refer to Note 12 for details on Certain Wages and Salaries relating to SOZO software development have been recognized installations and trainings are allocated to cost of revenue for the current prior corresponding periods. In addition, certain stallations and trainings are allocated to cost of revenue for the current prior corresponding periods.	reduction to expenses related this plan. Inised as Intangible Assets in ain wages and salaries directly	d to Wages and Salaries of accordance with AASB 138
Research and Clinical Trials	31 Dec 2019	31 Dec 2018
	\$000	\$000
Oncology Clinical Trials (i)	1,056	702
Cardiology and Other Clinical Trials (ii)	833	673
Product Engineering and other Research and Development	85	79
Total Research and Clinical Trials	1,974	1,454
(i) Oncology clinical trial costs include approximately \$258,000 of technical writing and s Meta-analysis manuscript in the current period. The Meta-analysis manuscript, which ever was submitted during the current period and awaits review and publication.  Cardiology trial costs increased in the current period due to work completed on the He at tool in the clinical assessment and treatment of HF patients. The manuscript is being and publication in the coming months.	valuated 50 studies comprising art Failure (HF) manuscript, w	g more than 17,000 patients, which uses bioimpedance as

Cardiology trial costs increased in the current period due to work completed on the Heart Failure (HF) manuscript, which uses bioimpedance as a tool in the clinical assessment and treatment of HF patients. The manuscript is being finalised and is expected to be submitted for peer review and publication in the coming months.

Administrative and Governance Fees	31 Dec 2019 \$000	31 Dec 2018 \$000
Governance and Regulatory Fees	506	383
Insurance	480	281
Foreign Currency Loss on Transactions	191	11
Administrative Expenses	176	118
Directors' Fees (i)	30	327
Total Administrative and Governance Fees	1,383	1,120

Expenses related to Directors' Fees were reduced during the current period as part of the Non-Executive Share Plan. Refer to Note 12 for details on this plan.

Consulting and Professional Fees	31 Dec 2019 \$000	31 Dec 2018 \$000
Professional Fees (i)	607	110
Consulting Fees (ii)	485	527
Patent and Trademark Fees	232	371
Total Consulting and Professional Fees	1,324	1,008

- (i) The increase in professional fees for the current financial period was primarily attributable to recruitment fees for the increase in sales and marketing headcount as part of US commercialisation efforts and the launch of the Lymphoedema Prevention Program ("LPP"), as well as legal fees.
- (ii) The decrease in Consulting Fees in the current period were a result of a decrease in R&D related consultant expenses. This decrease was partially offset by increases to marketing consulting for the launch of the LPP and reimbursement initiatives with MCRA.

Other Expenses	31 Dec 2019 \$000	31 Dec 2018 \$000
Depreciation and Amortisation (i)	646	299
Travel Expenses	548	707
Advertising and Promotion (ii)	530	268
IT, Property and Other Expenses	447	479
Total Other Expenses	2,171	1,753

The increase in Depreciation and Amortisation expense in the current period was primarily attributable to software development and other enhancements, as well as the implementation of AASB 16 *Leases*. Refer to Note 16 for details on AASB 16 *Leases*.

The increase in advertising and promotion expenses for the current financial period was primarily attributable to the design and implementation of the Lymphoedema Prevention Program.

# R Cash and Cash Equivalents

	As at 31 Dec 2019 \$000	As at 30 Jun 2019 \$000
Cash at Bank and in Hand	3,799	3,165
Short-term Deposits	9,172	8,165
Cash and Cash Equivalents	12,971	11,330

## 9. Trade and Other Receivables

5	As at 31 Dec 2019 \$000	As at 30 Jun 2019 \$000
Trade Receivables	787	800
Allowance for Expected Credit losses	(32)	(52)
Interest Receivable	17	18
Tax and Other Receivables	1,604	2,722
Total Trade and Other Receivables	2,376	3,488

# 10. Non-Current Assets – Intangible Assets and Goodwill

# Intangible Assets

Intangible assets, including goodwill, totaled \$6.0 million at 31 December 2019 (30 June 2019: \$5.4 million).

During the six months ended 31 December 2019, the Group generated intangible assets with a cost of \$1,040,000 (31 December 2018: \$946,000) related to the development of SOZO software. In accordance with AASB 138 Intangible Assets, the Group capitalises costs for product development projects. Initial capitalisation of costs is based on management's judgement that technological and economic feasibility is confirmed. In determining the amounts to be capitalised, management makes assumptions regarding the expected future cash generation of the project, discount rates to be applied and expected period of benefits.

Other intangible assets decreased in the current period due to the amortisation of SOZO software, computer software and licenses. This decrease was partially offset by foreign currency exchange movements.

#### Goodwill

Goodwill totaled approximately \$2.6 million at 31 December 2019 and 30 June 2019.

Goodwill is reviewed for impairment annually or more frequently if events or changes in circumstances indicate that the carrying value may be impaired.

At 31 December 2019, the Group found no evidence of impairment of goodwill or other assets, and as a result, no impairment loss has been recognised at the reporting date.

# 11. Issued Capital

Ordinary Shares

	Number of Shares	\$000
At 31 December 2018	378,993,655	219,744
Issued During the Period as a Result of:		
Employee Exercise of Options	810,332	96
Transaction Costs	-	(113)
At 30 June 2019	379,803,987	219,727
Issued During the Period as a Result of:		
Issue of Ordinary Shares from Capital Raisings	126,602,928	13,926
Employee Exercise of Options	775,566	85
Employee Performance Rights Issued	919,666	-
Non-Executive Director and Employee Share Plan Issuances	1,606,440	-
Transaction Costs		(992)
At 31 December 2019	509,708,587	232,746
12. Share-Based Payments		
	31 Dec 2019	31 Dec 2018
	\$000	\$000
\$hare-Based Payments to Employees	1,689	1,861
Share-Based Payments to Non-Executive Directors	310	

	31 Dec 2019	31 Dec 2018
	\$000	\$000
Share-Based Payments to Employees	1,689	1,861
Share-Based Payments to Non-Executive Directors	310	-
Total Share-Based Payments	1,999	1,861

#### **Executive and Non-Executive Share Plans**

During the period, the Group instituted an Executive Share Plan whereby up to 20% of an Executive's gross salary and short-term incentives and a Non-Executive Share Plan whereby 100% of Directors' Fees were taken as shares in lieu of cash. The Group established these plans to (a) align the financial interests of Executives and Directors with those of the shareholders, (b) facilitate the acquisition of shares by the Executives and Directors, and (c) preserve cash reserves by remunerating the Executives and Directors with shares in lieu of cash. Refer to the 2019 AGM Notice for full details of the plans.

During the period, share-based payments issued under the Executive Share Plan to Executives were approximately \$168,000 (31 December 2018: nil).

#### Share Options

Share options are issued to eligible participants under the EIP. Share options issued during the period vest on the one-year anniversary of the date of grant in an amount equal to the product of one-fourth multiplied by the number of total options granted. The remaining options vest evenly on an annual basis over the next three years if the participant is still employed on such dates. In a situation where there is likely to be a change of control of the Group, the Board may have the discretion to determine whether some, none or all of the LTI instruments will vest.

The fair value of the options granted is estimated at the date of grant using the Black Scholes model, taking into account the terms and conditions upon which the options were granted.

The weighted average fair value of the options granted during the six-month period was \$0.09 (31 December 2018: \$0.23).

During the current period, 8,684,808 share options (31 December 2018: 604,000) and 5,185,175 performance rights (31 December 2018: 310,000) were granted under the EIP. The awards granted included 4,764,623 share options (31 December 2018: 515,000) and 4,010,561 performance rights (31 December 2018: 310,000) granted to key management personnel ("KMP") during the period. The exercise price of the options was valued at the share price on the date of issue using the five-day weighted average share price.

The fair value of awards granted during the current period, were estimated on the date of grant using the following assumptions:

Assumptions	Options	Performance Rights
Expected Volatility (%)	73.45	N/A
Risk-Free Rate of Return (%)	2.62	N/A
Dividend Yield (%)	-	-
Average Expected Life (years)	4.60	3.00
Strike Price (\$)	0.15	-

## Performance Rights

Performance shares (or Performance Rights) are issued to eligible participants under the EIP in recognition of their contribution to the performance of the Group and are often subject to meeting individual performance hurdles.

All performance rights are issued at the discretion of the Board of Directors and are issued for nil consideration. The performance rights granted during the period vest in full on the third anniversary of the grant date. In the event of a change of control, all outstanding unvested performance rights may vest on an accelerated basis immediately.

If the participant ceases employment with the Group where such cessation of employment is due to the participant's death, permanent illness or

permanent physical or permanent mental incapacity (as certified by a medical practitioner who is approved in writing by the Board), the performance rights will fully vest on the third anniversary of the date of grant.

Performance rights which have not vested shall automatically lapse and be forfeited without consideration upon cessation of the participant's employment with the Group.

The fair value of performance shares is measured by using the stock price for ImpediMed Limited as of the close of business on the day prior to the grant date multiplied by the number of eligible shares. The number of eligible shares is measured using a combination of the probability of future service and the achievement of specific goals.

# 13. Related Party Disclosures

#### **Subsidiaries**

The consolidated financial statements include the financial statements of ImpediMed Limited and the subsidiaries listed in the following table:

Name	Country of Incorporation	% Equity Interest	
(D)		31 Dec 2019	31 Dec 2018
ImpediMed Incorporated	United States	100	100
ImpediMed Hellas	Greece	100	100
ImpediMed TM Incorporated	United States	100	100

#### **Ultimate Parent**

ImpediMed Limited is the ultimate parent entity.

Details relating to Directors are included in the Directors' Report.

For the half-year ended 31 December 2019, and for the prior half-year, no transactions with Directors occurred that would be considered related party transactions.

Terms and Conditions of Transactions with Related Parties

Sales to and purchases from related parties are made in arm's length transactions both at normal market prices and on normal commercial terms.

# 14. Commitments and Contingencies

#### **Expenditure Commitments**

At 31 December 2019, the Group has commitments of \$1.4 million (30 June 2019: \$2.2 million) relating to the funding of future product builds, clinical trials, advertising and promotional activities, and other activities. The expenditure commitments primarily relate to the commercialisation of the SOZO device with L-Dex technology in the US marketplace, as well as the PREVENT and CHF clinical trials.

# Contingent Liabilities

The Group had no contingent liabilities as at 31 December 2019.

## 15. Events After the Balance Sheet Date

#### January 2020

# independent studies continue to be submitted and released

An independent paper was published in Cancers, titled A Preoperative Assessment of Upper Extremity Secondary Lymphoedema. The paper, which was submitted by The Department of Surgery, Memorial Sloan Kettering Cancer Center, evaluated the most commonly used preoperative assessment tools for patients undergoing surgical treatment for secondary upper extremity lymphoedema. The report stated that the "L-Dex® score was found to be the most rapid and reliable non-invasive method for detecting early-stage lymphedema in this study".

# February 2020

# NCCN Guidelines® for Breast Cancer Updated for Lymphoedema

The NCCN Clinical Practice Guidelines for Breast Cancer (NCCN Guidelines®) were updated with new recommendations for early detection and diagnosis of lymphoedema to achieve optimal management. Additionally, healthcare providers are now encouraged to consider pretreatment baseline measurements for patients with lymphoedema risk factors.

The NCCN Guidelines® update follows a request by Vanderbilt University School of Nursing, Lymphedema Education and Research Network (LE&RN), and the American Society of Breast Surgeons Foundation to recommending add language establishing surveillance program with BIS to detect subclinical breast cancer-related lymphoedema (BCRL) and initiate early intervention to reduce the need for complete decongestive physiotherapy. pretreatment recommendation for baseline measurements to facilitate the earliest identification of subclinical lymphoedema was also requested.

The National Comprehensive Care Network® (NCCN®) documents recommendations for diagnostic, treatment, and supportive services provided to cancer patients. The NCCN Guidelines® are referenced by providers and payors when making decisions about care and coverage of oncology patient services. While the recent updates do not specify a measurement technique, they are consistent with the Test, Trigger, Treat™ protocol outlined in ImpediMed's Lymphoedema Prevention

Program (LPP), which is supported by evidence from the PREVENT Trial.

## February 2020

# Further Validation of SOZO by Macquarie University

Macquarie University, through its Australian Lymphoedema Education Research and Treatment (ALERT) team and Louise Koelmeyer, published a study comparing ImpediMed's SOZO and U400 devices. In the study, 100 women were assessed using both devices. SOZO measurements were taken in standing and seated positions while the U400 measurements were taken in standing, seated and supine positions.

The results from the study demonstrated that the L-Dex scores were highly correlated ( $r_c = 0.925$ ). They found that L-Dex measurements could be made reliably but not interchangeably with either device. There was as expected absolute difference between the SOZO standing and U400 supine due to the differences in electrode position.

The findings support impedance measurements being made reliably using either the leaded or stand-on device representing supine and upright measurement positions respectively. This work is important as it provides peer-reviewed clinical evidence that studies which have been previously conducted on the U400 can be applied to SOZO.

# 16. Changes to the Group's Accounting Policies

#### Impact of AASB 16 Leases

AASB 16.C12 AASB 16 supersedes AASB-117 Leases, IFRIC 4 Determining whether an Arrangement contains a Lease, SIC-15 Operating Leases-Incentives and SIC-27 Evaluating the Substance of Transactions Involving the Legal Form of a Lease. The standard sets out the principles for the recognition, measurement, presentation and disclosure of leases and requires lessees to recognise most leases on the balance sheet.

The Group adopted AASB 16 using the modified retrospective method of adoption with the date of initial application of 1 July 2019. Under this method, the standard is applied retrospectively with the cumulative effect of initially applying the standard recognised at the date of the initial application.

Upon adoption of AASB 16, the Group applied a single recognition and measurement approach for all leases for which it is the lessee. The Group recognised lease liabilities based on the present value of the remaining lease payments, discounted using the incremental borrowing rate at the date of initial application of 7.68%. The Group recognised right of use assets based on the carrying amount as if the standard had always been applied, apart from the use of incremental borrowing rate at the date of initial application.

On adoption of the new standard the Group elected to use the following transition practical expedients:

- to not reassess whether a contract is, or contains a lease at 1 July 2019. Instead, the Group applied the standard only to contracts that were previously identified as leases applying AASB-117 and IFRIC 4 at the date of initial application.
- to use a single discount rate to a portfolio of leases with reasonably similar characteristics.
- to use hindsight in determining the lease term where the contract contained options to extend or terminate the lease.

The following was the impact on adoption of AASB 16 at 1 July 2019:

	1 July 2019 \$000
Assets	
Right of Use Assets	943
Total Assets	943
Liabilities	
Lease Liabilities	(994)
Deferred Rent	84
Total Liabilities	(910)
Equity Adjustment (accumulated losses)	(33)

The lease liabilities as at 1 July 2019 can be reconciled to the operating lease commitments as of 30 June 2019, as follows:

		1 July 2019 \$000
	Operating lease commitments as at 30 June 2019	(1,024)
Ī	Weighted average incremental borrowing rate as at 1 July 2019	7.68%
Ī	Discounted operating lease commitments as at 1 July 2019	(994)
1	Adjusted for deferred rent previously recognised	84
7	Lease liabilities as at 1 July 2019	(910)

At 31 December 2019, the Right of Use assets totaled \$782,000 and the lease liability totaled \$833,000.

# 17. Discontinued Operations

In October 2018, the Group announced that it agreed to divestiture of XiTRON Technologies, ("XiTRON"), a wholly owned subsidiary of the Parent. Under the terms of the agreement, the Group agreed to sell the majority of the net assets of the test and measurement ("T&M") business. The T&M business of XiTRON represented the entirety of the Group's T&M operating segment through its closure in October 2018.

During the current financial period, the Group applied AASB 5 Non-Current Assets Held for Sale and Discontinued Operations as part of accounting for the divestiture of XiTRON Technologies, Inc. and the T&M operating segment. The entirety of the transaction

occurred during the previous financial period. AASB 5 prohibits the retrospective classification as discontinued operating, when the discontinued criteria are met after the end of the reporting period.

With the T&M business of XiTRON being classified as a discontinued operation, the T&M operating segment is no longer presented as a distinct operating segment. Refer to Note 4 Segment Reporting for additional information on segment reporting.

The result of the test and measurement operating segment for the year ended 30 June 2019 are presented as follows:

	31 Dec 2018 \$000
Revenue from Contracts with Customers	292
Expenses	(386)
Operating Loss	(94)
Impairment Loss Recognised on the Remeasurement of Fair Value Less Costs to Sell	(33)
Loss for the Year from Discontinued Operations	(127
Proceeds from the Disposal of a Business, Net of Disposal Costs	467
Net Assets Associated with Discontinued Operations	594
Loss for the Year from Discontinued Operations	(127
·	,
	31 Dec 2018
	\$000
Operating	**
Investing	
Financing	
Net Cash Flow	
$(\mathcal{O}(\mathcal{O}))$	

	31 Dec 2018 \$000
Operating	8
Investing	-
Financing	-
Net Cash Flow	8

# **Directors' Declaration**

For the half-year ended 31 December 2019

In accordance with a resolution of the Directors of ImpediMed Limited, we state that:

In the opinion of the Directors:

- (a) The financial statements and notes of the consolidated entity for the half-year ended 31 December 2019 are in accordance with the Corporations Act 2001, including
  - (i) giving a true and fair view of the consolidated entity's financial position as at 31 December 2019 and of its performance of the half-year ended on that date; and
  - (ii) complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the Corporations Regulations 2001.

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

Scott Ward Chairman

Judith Downes Director

20 February 2020



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# Independent Auditor's Review Report to the Members of Impedimed Limited

# Report on the Half-Year Financial Report

## Conclusion

We have reviewed the accompanying half-year financial report of ImpediMed Limited (the Company) and its subsidiaries (collectively the Group), which comprises the balance sheet as at 31 December 2019, the statement of comprehensive income, statement of changes in equity and statement of cash flows for the half-year ended on that date, notes comprising a description of significant accounting policies and other explanatory information, and the directors' declaration.

Based on our review, which is not an audit, nothing has come to our attention that causes us to believe that the half-year financial report of the Group is not in accordance with the Corporations Act 2001, including:

- giving a true and fair view of the consolidated financial position of the Group as at 31 December 2019 and of its consolidated financial performance for the half-year ended on that date; and
- complying with Accounting Standard AASB 134 Interim Financial Reporting and the Corporations Regulations 2001.

# Emphasis of Matter - Material Uncertainty Related to Going Concern

We draw attention to Note 1 in the financial report, which indicates that the Group incurred a net loss of \$12.9 million during the period ended 31 December 2019 (31 December 2018: \$12.3 million) and is dependent on sufficient cash inflows from growth in future sales, capital raises or other funding arrangements. These events or conditions indicate that a material uncertainty exists that may cast significant doubt on the Group's ability to continue as a going concern. The financial report does not include any adjustments relating to the recoverability and classification of recorded asset amounts or to the amounts and classification of liabilities that might be necessary should the entity not continue as a going concern. Our opinion is not modified in respect of this matter.

# Directors' Responsibility 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 is free from material misstatement, whether due to fraud or error.



# Auditor's Responsibility

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, anything has come to our attention that causes us to believe that the half-year financial report is not in accordance with the Corporations Act 2001 including: giving a true and fair view of the Group's consolidated financial position as at 31 December 2019 and its consolidated financial 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 the Group, 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*.

Ernst & Young

Ernst & Young

Jennifer Barker Partner Brisbane

20 February 2020

