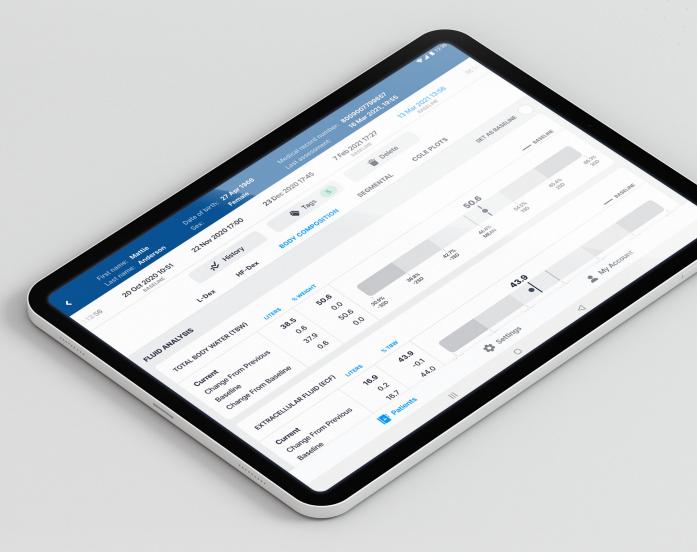
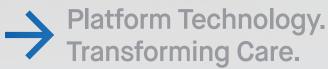
# Interim Financial Report

For the Half-Year Ended 31 December 2021





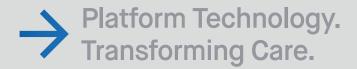


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# Corporate Information

**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**

D Williams, Chairman (Appointed Chairman 10 November 2021)

S Ward, former Chairman (Retired 10 November 2021)

D Anderson

J Downes

R Graham

A Patel

# **Managing Director**

R Carreon, Managing Director and CEO

# **Company Secretary**

L Ralph

# Locations

# **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".

### **Websites**

www.impedimed.com www.preventlymphedema.com

### The PREVENT Trial:

https://www.impedimed.com/stopping-lymphedemastarts-with-prevent/

### **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**

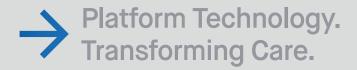
Ernst & Young Level 51, 111 Eagle Street Brisbane QLD 4000

# Remuneration Advisors to the Board of Directors

Aon – Rewards Solution 425 Market Street, Suite 2800 San Francisco CA 92105 US

# 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 2021.

# **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. Please refer to the 2021 Annual Report or ImpediMed's website for full bios on the Directors.



Donald Williams
BAcy, CPA
Non-Executive Chairman
(Appointed Chairman 10 November 2021)



David Anderson
BSc
Non-Executive Director
Chair, Remuneration Committee



Judith Downes
BA(Hons), DipEd
GradDipBus(Acct), FAICD,
FCPA, FCA
Non-Executive Director
Chair, Audit and Risk Management
Committee



Robert Graham

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



Amit Patel MBA, BME 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).

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

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

The Group is initially focused on three large and growing markets: Oncology, Heart Failure, and Renal Failure. These markets overlap significantly and represent an annual addressable market of over \$2.0 billion.

# Oncology Heart Failure

Lymphoedema Protein Calorie Malnutrition<sup>^</sup>

Fluid Overload Protein Calorie Malnutrition^

A\$1+ billion

A\$700+ million

# Renal **Failure**

Fluid Overload Protein Energy Wasting<sup>^</sup>

A\$300+ million

^In Renal Failure, the terms Protein Calorie Malnutrition (PCM) and Protein Energy Wasting are often used interchangeably. ImpediMed most commonly refers to this disease state as PCM.

SOZO measures and tracks critical patient data. A single SOZO measurement provides:

- L-Dex® lymphoedema index
- Total body water
- Extracellular fluid
- Intracellular fluid
- Skeletal muscle mass
- Fat mass
- Fat-free mass

- HF-Dex<sup>TM</sup> heart failure index
- · Protein and minerals
- · Basal metabolic rate
- · Phase angle
- · Body mass index
- Segmental analysis
- Hy-Dex® hydration analysis¹

<sup>1</sup> Hy-Dex® hydration analysis is only intended for use with healthy individuals

# **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.

# **Key Corporate Data**

Share price^	\$0.18
Shares on issue^	1,777 million
Market Capitalisation <sup>^</sup>	\$320 million
Cash (31 December 2021)	\$50.8 million
Share Register Breakdown	Institutional 49%
(31 December 2021)	Private 48%
	Board/Employee
	3%

<sup>^</sup>Data as of 23 February 2022

For more information, visit: <a href="https://www.impedimed.com/">https://www.impedimed.com/</a>.

# **Connected Digital Health Platform**

SOZO, the world's most advanced, noninvasive bioimpedance spectroscopy (BIS) device, delivers a precise snapshot of fluid status and tissue composition in less than 30 seconds. Results are available immediately online for easy data access and sharing across an entire healthcare system. The FDA-cleared, CE-marked and ARTG-listed digital health platform aids in the early detection of secondary lymphoedema, provides fluid status for patients living with heart failure, and can be used to monitor and maintain overall health – all on a single device.

Access

Test patients at any location and immediately review results online.

**Trends** 

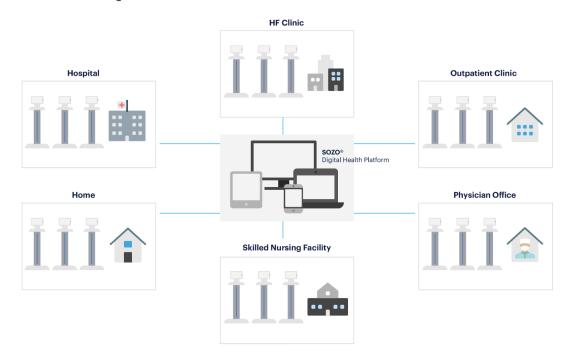
Track trends in patient data for actionable results.

Scalable

Add and move test locations without any additional software setup.

Secure

Control who accesses the HITRUST certified SOZO network and establish unique security settings.



# **The Lymphoedema Prevention Program**

# Together, We Can End Cancer-Related Lymphoedema

The Lymphoedema Prevention Program is a comprehensive approach to eliminating breast cancer-related lymphoedema. Lymphoedema is no longer an unpreventable side effect of cancer treatment.

- ImpediMed's Lymphoedema Prevention Program integrates into current practice to achieve optimal patient outcomes.
- Optimal patient care is achieved through positive health economics.

The Lymphoedema Prevention Program follows a defined protocol for optimal patient outcomes:

# **Test**

Test all patients at-risk of lymphoedema using SOZO with L-Dex

- 4 times per year
- 3 years
- 2 times per year in years 4 and 5

# Trigger

L-Dex increase of 6.5 or more from baseline indicates a likelihood of subclinical lymphoedema

# Treat

At-home treatment with compression garments

- 4 weeks
- 12 hours per day

# The PREVENT Trial

The results of the PREVENT Trial are in and they are conclusive. These results allow for an evidence-based approach to improving patient outcomes.

PREVENT is the largest Level I randomised trial ever to assess subclinical lymphoedema detection:

# Lymphoedema is Preventable

With Early Detection and Intervention

# The PREVENT Trial

- Level 1 evidence: largest randomised controlled trial (RCT) to assess lymphoedema prevention
- · 1,200 breast cancer patients followed for 3 years
- 10 centers, including 6 NCCN/NCI centers, across the US and Australia
- · Met primary endpoint
- · Statistically significant results

92% of patients

with early detection using L-Dex® and intervention did not progress to chronic lymphedema

"[L-Dex] screening should be a standard approach for prospective breast cancer-related lymphedema surveillance" – The PREVENT Trial

Ridner SH, et al. A Comparison of Bioimpedance Spectroscopy or Tape Measure Triggered Compression Intervention in Chronic Breast Cancer Lymphedema Prevention. Lymphatic Research and Biology 2022.

# **Milestones**

For the half-year ended 31 December 2021 and through the date of this report, the Group executed on a number of key milestones across all three strategic focus areas: Oncology, Heart Failure and Renal Failure.

# **ONCOLOGY**

# PREVENT

1 February 2022

### **PREVENT Trial Peer Reviewed and Published**

The Group announced that the PREVENT trial results have been peer-reviewed and published in *Lymphatic Research and Biology*, a journal dedicated to research on lymphatic biology and pathology from the world's leading biomedical investigators. The study demonstrated that intervention in patients with early detection of cancer-related lymphoedema using ImpediMed's L-Dex technology resulted in a lower rate of progression to chronic disease than patients with early detection from volume measurements using a tape measure, a result that is statistically significant.

The results were as follows:

- The trial met its primary endpoint.
- In patients with early detection using L-Dex, intervention resulted in a 7.9% rate of chronic lymphoedema compared to a 19.2% rate of chronic lymphoedema in patients with early detection using tape measure (p=0.016).
- This represents an absolute reduction of 11.3% and relative reduction of 59%.
- 92% of patients with early detection of cancer-related lymphoedema using L-Dex and intervention did not progress to chronic lymphoedema.
- A risk-adjusted analysis showed a significantly consistent benefit of L-Dex monitoring in a large group of patients with key risk factors for BCRL including body weight, stage of cancer, type of cancer surgery, lymph node dissection, chemotherapy, and radiation (odds ratios: 0.23-0.39).

The paper concluded the following:

- These statistically significant results demonstrate that bioimpedance spectroscopy (BIS) screening should be a standard approach for prospective breast cancer-related lymphoedema surveillance.
- BIS is more specific for lymphoedema detection than tape measure (TM), as it had fewer triggers and longer times to intervention trigger.
- While the BIS protocol can be easily replicated in clinical settings, the rigor of the TM protocol for this study
  exceeded what is practical in most clinics. Thus, BIS may offer even more benefit across clinical settings than
  what was demonstrated in this study.
- BIS, as compared to TM, provides a more precise identification of patients likely to benefit from an early compression intervention.

The PREVENT trial is a seminal study, the largest randomised controlled trial to be conducted on patients at-risk of lymphoedema. The study enrolled >1200 patients across 10 trial sites in the US and Australia, involving 13 hospitals. Of these, 3 of the 9 US sites are National Comprehensive Cancer Network® (NCCN) Member Institutions. The trial was conducted over six and a half years and patients were followed for up to three (3) years, with primary aim to determine if subclinical detection of extracellular fluid accumulation via bioimpedance spectroscopy, and subsequent early intervention, reduces the rate of lymphoedema progression relative to the rate when using tape measurements.

<sup>&</sup>quot;...We reached a significant milestone that will change the trajectory of the company. Randomised trials of this size are the highest level of scientific evidence and PREVENT will help us expand access to L-Dex testing for millions of patients worldwide. PREVENT shows to the world that our bioimpedance spectroscopy (BIS) technology can detect medically meaningful fluid shifts in the body."

<sup>-</sup> Richard Carreon, Managing Director and CEO of ImpediMed

# CASE ASSISTANCE PROGRAM

31 January 2022

## Significant Momentum Building with ImpediMed's Case Assistance Program

ImpediMed's Case Assistance Program is available to all SOZO customers. The program handles all processes required for reimbursement, facilitates patient access to testing, and is fully compliant with HIPAA and guidance from the Office of the Inspector General. The Group gave an update as part of its Appendix 4C Quarterly Investor Conference Call on the progress made with the Case Assistance Program as of 31 January 2022:

- The Group has won 1,723 cases with commercial payors, up from 298 at the time it was last reported [during the October capital raising ("Oct 21 CR")].
- The Group has won 96% of all cases to date with target payors (97% Oct 21 CR).
- There are still over 1,800+ active cases (1,300+ at Oct 21 CR).



30 September 2021

# **New Corporate Oncology Account with Icon Group**

The Group announced an agreement with Icon Group for the rollout of the initial 13 SOZO units to establish lymphoedema screening services for breast cancer patients across Australia and New Zealand.

Icon Group is Australia's largest dedicated cancer care provider with 31 cancer centres in Australia and a global footprint in New Zealand, Singapore, Hong Kong and mainland China. This footprint includes day oncology hospitals, radiation oncology facilities and comprehensive centres that bring both oncology disciplines together.

With a commitment to delivering the best care possible, closer to home for cancer patients through the use of innovative technology-based solutions, Icon offers the latest in cancer treatment including Australia's largest private cancer clinical trials program to improve health outcomes for men and women both in Australia and across the world.

# **HEART FAILURE**



4 November 2021

## AstraZeneca Extended and Increased its SOZO for Heart Failure & Renal Failure Contract

AstraZeneca extended and increased its contract for SOZO, which is being used in a Phase II trial to measure and track fluid volume in patients with heart failure and chronic kidney disease. The study is evaluating the efficacy, safety, and tolerability of a combination of two AstraZeneca drugs in heart failure patients with chronic kidney disease. The study has been extended from 18 months to 21 months and the number of SOZO devices increased from 175 to 211. The extension and expansion of the trial will generate an estimated value of over \$0.5 million in additional revenue to be recognised in coming quarters. In total, AstraZeneca will lease up to 411 SOZO devices across the various contracts, valued at over \$5.0 million in revenue.



27 September 2021

# SOZO Heart Failure Program Initiated at AdvocateAuroraHealth

The Group announced the inaugural SOZO Heart Failure Program has been established at Advocate Health Care's Heart Institute, Chicago, Illinois. The introduction of SOZO is being championed by Dr Ali Valika, MD, an interventional cardiology specialist board certified in Advanced Heart Failure and Transplant Cardiology, with the aim of optimising fluid levels in Heart Failure Patients both in clinic and after discharge.

The Group was able to leverage its existing footprint within the Advocate Aurora Health system to move forward with an initial Heart Failure Program. The Advocate Aurora Health system currently has 10 SOZO devices under a Lymphoedema Prevention Program.

AdvocateAuroraHealth consists of 26 hospitals and over 500 sites of care. Advocate Health Care in Illinois and Aurora Health Care in Wisconsin together form one of the premier, not-for-profit health systems in the United States. Advocate Aurora Health is nationally recognised for clinical expertise across the care continuum while leading health care transformation to drive value and reimagine the consumer experience.

Within Advocate Health Care is the Advocate Heart Institute with over 100 sites, where 350 specialists perform more than 20,000 heart procedures each year, the most in Illinois. They are a national leader in heart outcomes and pride themselves on pioneering the most advanced programs and technology.



13 September 2021

# HFSA Abstracts Demonstrate the Utility of SOZO for HF Patients

The Group announced two abstracts were presented in the poster session of the prestigious Heart Failure Society of America (HFSA) Annual Scientific Meeting September 10 – 13, 2021. The abstracts were from studies conducted at Scripps Memorial Hospital campuses and were accepted in the Clinical Care category.

The abstracts were as follows:

# Time to decongestion following heart failure hospitalization as measured by extracellular fluid nadir using bioimpedance spectroscopy (BIS)

This was a multi-centre observational study evaluating volume status of heart failure patients recently discharged from hospital and undergoing a diuretic regimen, with reducing extracellular fluid (ECF) being the main objective of therapy. The study undertook daily SOZO BIS measurements to track fluid status and compared them to corresponding weight measurements. It took an average of 16.9 days for patients to reach their lowest extracellular fluid volume following a heart failure-related hospital stay. During this time, patients experienced more than a two-fold ECF loss as compared to weight loss on a percentage basis, demonstrating the sensitivity of BIS as diuretic decongestion reduces ECF.

**The abstract concluded:** Frequent monitoring of ECF using BIS Measurements, is a more sensitive method than weight to monitor fluid status in patients with heart failure and may help guide diuretic therapy after hospitalisations.

# Bioimpedance spectroscopy offers an objective measure of heart failure stability during a viral pandemic

The abstract addressed a concern that patients with heart failure related congestion were potentially being misclassified and diuretic therapy delayed when presenting with shortness of breath during the COVID-19 pandemic. The study assessed 56 heart failure patients during the COVID-19 pandemic. SOZO HF-Dex measurements were obtained upon visitation. The paper observed patients with HF-Dex measurements of ≥51% required higher rates of medication and diuretic changes. These patients also felt worse which may limit misclassification of congestion when shortness of breath is the main complaint.

The abstract poster concluded: The ability to quantify congestion using BIS measures, may assist in triage of patients presenting with shortness of breath, as increasingly (has) been the case during the COVID-19 pandemic, in clinic and acute care settings.

# **RENAL FAILURE**



23 August 2021

# FDA Grants Breakthrough Device Designation for Renal Failure

The Group announced SOZO has received FDA Breakthrough Device Designation for a proposed indication in a renal patient population.

The Group intends to use its well-established SOZO bioimpedance spectroscopy (BIS) platform to provide an exact measure of fluid volume to remove during a dialysis session. The current process, utilising weight scales to determine accumulation of fluid, has significant deficiencies. The scales cannot account for changes in body composition, with muscle loss being prevalent in end-stage renal disease patients. The potential for SOZO to address this deficiency was paramount in meeting the criteria for Breakthrough Designation.

The US Breakthrough Device Designation is granted when a device is shown to meet the following criteria:

- The device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions
- The device must also meet one or more of the following criteria:
  - Represents breakthrough technology
  - No approved or cleared alternatives exist
  - o Offers significant advantages over existing approved or cleared alternatives
  - Device availability is in the best interest of patients

There are many benefits associated with acceptance into the Breakthrough Program, with the FDA allocating specific resources throughout the development process to maximise the impact of the program. The benefits include:

- Interactive and timely communication
  - FDA provides interactive and timely communication during device development and throughout the review process.
- Efficient and Flexible Clinical Study Design
  - FDA collaborates to ensure the design of clinical trials is efficient and flexible.
  - This can include prespecified endpoints, the use of surrogate endpoints and adaptive study designs.
  - o Importantly, the Breakthrough Program includes a provision for obtaining a binding agreement on clinical protocols.
- Priority Review
  - Breakthrough Devices receive priority review and
  - Receive additional review resources, as needed.

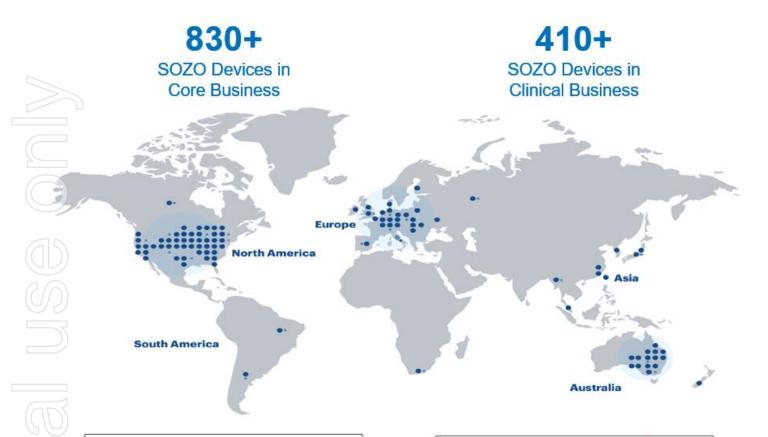
A breakthrough designation positions ImpediMed to successfully expand its SOZO platform into the renal space. ImpediMed will partner with the FDA to expedite the development and clearance of SOZO. The breakthrough sprint sessions are the perfect forum to develop the clinical evidence plan, including trial design, to obtain data that will result in a successful clearance to market.

"Dry weight assessment and appropriate fluid removal during dialysis remains a significant challenge for nephrologists. Clinical assessment alone appears to be inadequate in many dialysis patients, especially those with multiple coexisting illnesses (cardiovascular disease, diabetes etc.). Both inadequate fluid removal and excessive fluid removal resulting in hypotension may adversely affect quality of life, increase hospitalisations and increase mortality."

"A device that can quickly and easily be used in the dialysis setting to accurately measure fluid volume is currently not FDA approved and readily available. Such a device may significantly improve quality of care and improve patient outcomes."

- Dr Mark M Boiskin MD FACP, Balboa Nephrology Medical Group & California Institute of Renal Research

# **Strong Adoption, Validated Technology**





This equates to SOZO units in more than one-third of the NCCN/NCI centres.



As of 31 December 2021, not all units for the AstraZeneca trials were yet deployed.



























# **Technology Adoption**

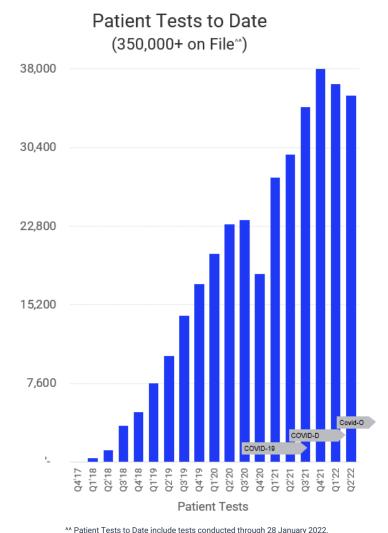
# **SOZO Patient Tests**

As of January 2022, ImpediMed's customers have conducted more than 350,000 patient tests since the initial launch of SOZO, including over 71,000 in the first half of FY'22 alone, a 26% increase year over year.

To date, our growing patient database now has more than 1 billion individual data points that have allowed us to:

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

Although the Group continues to see robust growth, patient testing growth slowed due to the increased COVID-19 restrictions in hospitals across the US and COVID-19 variant related shutdowns in Australia. Despite choppiness in testing due to COVID-19, there is data showing the SOZO technology is starting to become standard of care in major cancer centres. COVID-19 has come in three waves: the original strain, the Delta variant, and the Omicron variant. During the first spike from the original strain, less than half of the installed SOZO devices in the US tested patients. During the spike in hospitalisations brought on by the Delta variant, more than two-thirds of the installed SOZO devices in the US tested patients. During the record spike in hospitalisations for the Omicron variant, more than 80% of installed SOZO devices were testing patients. While the spikes caused fewer patients to be tested, more devices were testing the patients that were able to come in for treatment.



COVID-D refers to the Delta variant. COVID-O refers to the Omicron variant.

# **Operating and Financial Review**

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

### Revenue

Total Revenue for the six-month period ended 31 December 2021 was \$5.2 million an increase of 45% from the previous corresponding period (31 December 2020: \$3.6 million) despite the ongoing headwinds from the global COVID-19 pandemic. The increase in revenue was attributable to the SOZO product line and the continued strength of the Group's Software-as-a-Service (SaaS) business model.

SOZO Revenue for the current period was \$4.9 million (31 December 2020: \$3.3 million), an increase of 49% over the previous corresponding period. Of the SOZO revenue, \$4.3 million related to SaaS revenue (31 December 2020: \$2.3 million), an 82% increase over the previous corresponding period. SOZO Revenue is split between the Core Business, commercialisation efforts from the Group's core strategic focus areas with contracts that are ongoing in nature, and the Clinical Business, revenue generating contracts related to clinical trials that are finite in nature as they relate to clinical trials with specific end dates. This increase in revenue was attributable to SOZO commercialisation efforts in both the Core Business and Clinical Business.

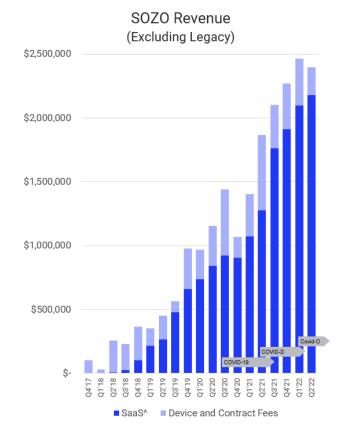
### **CORE BUSINESS**

Device and Contract Fees: This refers to revenue recognised at the onset of a contract. As of 31 December 2021, there were more than 830 SOZO units in the market (31 December 2020: 685 SOZO units), representing a 21% increase in the number of units sold, when compared to 31 December 2020. To date, the majority of device sales are in the Oncology market. While new unit sales during the period were no doubt impacted by COVID-19 headwinds, the quality of accounts that were closed were exceptionally high. With the addition of new SOZO contracts during the period, the Group now has 36 NCCN/NCI Member Institutions utilising SOZO.

Software-as-a-Service (SaaS): This refers to recurring SOZO subscription revenue. SaaS revenue generated by the Core Business was \$2.6 million (31 December 2020: \$2.0 million), which increased 33% over the prior period. During the period, the Group expanded its footprint in world-class cancer centres such as the University of Kansas and Memorial Sloan Kettering.

### CLINICAL BUSINESS

Software-as-a-Service (SaaS): SaaS revenue generated by the Clinical Business was \$1.65 million (31 December 2020: \$0.37 million), which increased 345% over the prior period. During the period the Group continued to recognise revenue within the Clinical Business, with the two largest contracts being the AstraZeneca studies. Approximately 411 SOZO devices will be leased across 28 countries for the two studies. These contracts are valued at over \$5.0 million with an end date currently expected in the first half of FY'23.



\$8.4m
ARR
+ 7%
YOY

\$14.3m CRP - 3%

90%+
SaaS GROSS MARGINS

2%
CHURN RATE
99% Renewal Rate

### SaaS Financial Metrics

In addition to revenue recognised during the current period, Annual Recurring Revenue (ARR) at 31 December 2021 totaled \$8.4 million (31 December 2020: \$7.8 million), an increase of 7% over the previous corresponding period. ARR from Core Business at 31 December 2021 totaled \$6.7 million (31 December 2020: \$4.9 million) an increase of 37% over the previous corresponding period. During the period, more than half of the US units sold were to new accounts and the Group has now sold more than 830 units since the launch of SOZO. As the Group begins to capitalise on the strength of the PREVENT Trial data and the success of reimbursement through the Case Assistance Program, we will now be well placed to accelerate the expansion of our technology and Annual Recurring Revenue in the coming quarters.

Contracted Revenue Pipeline (CRP) at 31 December 2021 totaled \$14.3 million (31 December 2020: \$14.8 million), a decrease of 3% over the previous corresponding period. The primary driver for the decrease is the recognition of revenue under the AstraZeneca clinical trials, which are scheduled to be fully recognised in the 2023 financial year.

Gross Margins were 97% on SaaS revenue for the six-month period. The Group anticipates 90%+ margins on the full \$14.3 million in CRP, when that revenue is recognised in the coming quarters.

The Churn Rate remained negligible at 2% globally. In addition, the Group renewed 99% of the contracts up for renewal during the six-month period. The small impact to the renewal rate stemmed from a few small practices with operational and financial constraints due to COVID-19 related challenges.

# Operating Results - Investing in Large, Growing Markets

Total comprehensive loss from operations for the period was \$8.5 million (31 December 2020: \$11.6 million). The decreased loss from operations, when compared with the prior period, is primarily attributed to an increase in revenue from the Group's high margin SaaS revenue, while keeping operating expenses flat period over period.

Cost of goods sold for the current period totaled \$0.8 million (31 December 2020 \$0.8 million). There was an increase in device and usage fee costs in the current period from higher unit sales and implemented units in the clinical business, which was offset by a reversal of inventory provision on legacy products, compared to the prior period.

Salaries and benefits for the period ended 31 December 2021 totaled \$7.8 million (31 December 2020 \$8.5 million). Salaries increased slightly compared to the prior period, which were offset by a decrease in short-term incentives.

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.

<sup>^</sup> YOY denotes Year-over-Year change in metric.

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

The values shown for total ARR and CRP across all lines of business, including the Core Business and Clinical Business. Refer to page 19 for a Glossary of Terms used by ImpediMed.

# \$50.8m CASH ON HAND 1H FY'22

\$5.1m Cash Receipts from Customers \$(6.3)m

Net Operating Cash
Outflow

\$42.5m Gross Proceeds from Placement & SPP

\* In addition to the items noted above, the change in cash on hand is also impacted by investing activities, other financing activities, and foreign exchange movements.

# **Review of Financial Condition – Liquidity and Capital Resources**

Cash and cash equivalents were \$50.8 million at 31 December 2021 (30 June 2021: \$19.0 million). Net cash used in operating activities for the period ended 31 December 2021 was \$6.3 million (31 December 2020: \$6.6 million). The decrease in operating cash outflow was primarily attributable to increased cash receipts from customers and a decrease in payments to suppliers.

Cash receipts for the period were \$5.1 million, an increase of \$1.8 million, or 55%, compared to the prior corresponding period cash receipts of \$3.3 million.

Cash outflow from investing activities was \$2.9 million during the period (31 December 2020: \$1.0 million). The increase in cash flows used in investing activities is primarily related to development costs (which are capitalised) associated with SOZO II hardware, in addition to continued software development costs.

During the period, cash inflows from financing activities were \$40.0 million (31 December 2020: \$7.9 million). The Group raised \$35.0 million before costs from a Placement, through an issuance of shares to new and existing investors. A further \$7.5 million before costs was raised from the issuance of shares under a Share Purchase Plan (SPP). Both the Placement and SPP were heavily over-subscribed.

# 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 \$0.75 and AUD \$1.00 to USD \$0.73, respectively. The spot exchange rate for the beginning and end of the prior reporting period was AUD \$1.00 to USD \$0.69 and AUD \$1.00 to USD \$0.77, respectively. This fluctuation of the exchange rate led to a favourable outcome in reporting cash and cash equivalents but led to an unfavourable outcome in operating expenditure when compared to the prior period.

The average exchange rate for the reporting period was \$0.73 (Australian dollar (AUD) to US dollar (USD)) (six-month period ended 31 December 2020: \$0.72). During the period, the Group incurred unrealised mark-to-market foreign currency translation losses of \$2,000 (six-month period ended 31 December 2020: \$26,000). 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.

Glossary of Terms used by ImpediMe	ed
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.
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.
Total Contract Value (TCV) (i)	The total value of customer contacts including one-time and recurring revenue.
Churn (i)	The total devices placed with end-user customer(s) who either (i) canceled while under their contracted period or (ii) elected not to renew their contract at the end of the contracted period.
Churn Rate (i)	[ Churn ] / [ (Total device placements at beginning of period + Total device placements at end of period) / 2 ]
Renewal Rate (i)	[ Total number of end-user customer contracts with expiration dates during the period that were retained ] / [ Total number of customer contracts with expiration dates during the period ]
Core Business	The Core Business refers to the commercialisation efforts from the Company's core strategic focus areas. To date, this primarily includes revenue from SOZO contracts in the Oncology market.
Clinical Business	The Clinical Business refers to revenue generating contracts related to clinical trials. These contracts are often finite in nature, as they relate to clinical trials with specific end dates
(i) ARR, CRP, TCV, and other SaaS related terms are useful Australian Accounting Standards.	unaudited, non-AASB financial metrics that do not represent revenue in accordance wi

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

# Significant Events after the Balance Sheet Date

# Issuance of Ordinary Shares - Equity Share Plans

On 6 January 2022, the Group issued 1,083,112 shares to Non-Executive Directors and Executives as part of the Equity Share Plans, related to the Q2 FY'22 performance period covering 1 October 2021 – 31 December 2021. These shares were issued in lieu of cash remuneration, which comprised 60% of Directors' fees and up to 20% of Executives' base salaries.

### PREVENT Trial Peer Reviewed and Published

The Group announced that the PREVENT trial results have been peer-reviewed and published in *Lymphatic Research and Biology*, a journal dedicated to research on lymphatic biology and pathology from the world's leading biomedical investigators.

# Clinical Trial Agreement announced for the SOZO Platform in Patients with End Stage Renal Disease (ESRD)

The Group announced it has entered into an agreement with balboa RESEARCH SMO+ ("Balboa") and Frenova Renal Research, a Fresenius Medical Care company, to conduct an initial Observational Trial. Dr Mark Boiskin and Dr Dylan Steer have agreed to serve as Principal Investigators for both the Observational Trial and a pivotal Interventional Trial, which will be used to support an application for FDA clearance for use of the device for patients with ESRD.

# New Bone Data Comparing ImpediMed's SOZO to DXA in Cancer Patients to be Presented at 39th Annual Miami Breast Cancer Conference

The Group announced that an abstract comparing concurrent measures using ImpediMed's SOZO® Digital Health Platform and dual x-ray absorptiometry (DXA) for assessing bone mineral content in cancer patients was accepted for poster presentation at the 39th Annual Miami Breast Cancer Conference on 3-6 March 2022 in Miami Beach, Florida, USA. The abstract titled "The Routine Use of Bioimpedance Spectroscopy Measurements in the Clinic as a Surrogate for Bone Mineral Content in Oncology Patients: Practical Application of the SOZO Device" analyses data collected using both SOZO and DXA in healthy participants and cancer patients.

Refer to Milestones on page 10 of this report for a detailed listing of additional significant events after the balance sheet date.

# **Likely Developments and Expected Results**

The following are areas of focus for the Group, as well as likely developments expected to impact the Group's financial results in the near-term:

# **CORPORATE**

- Continue growth in sales and the adoption of SOZO.
- Complete SOZO II development for Heart Failure and Renal Failure indications.
- Launch software Version 5.0 with data and software enhancements focused on corporate accounts.

# **ONCOLOGY**

- Principal Investigators to submit NCCN Guidelines<sup>®</sup> application in February 2022.
- Continue to expand case assistance program for private payor coverage/payment for L-Dex<sup>®</sup> testing.
- Land and expand key cancer centres, medical oncology groups and corporate accounts.
- Allocate resources to key growth areas based on positive trends developing in installed devices and utilisation.
- Expand private payor coverage/payment for L-Dex testing.

# **HEART FAILURE**

- Expand commercial sales of SOZO for Heart Failure through additional pilot programs in key heart failure centres.
- Gather real world data on reimbursement utilising SOZO through HF pilot programs.
- Continue to work with FDA on obtaining clearance for removal of SOZO contraindications for implantable pacing and cardioverter defibrillators devices.

# RENAL FAILURE

- Observational Study to be commenced, with an anticipated completion date of Q4 FY22.
- Partner with the FDA and Principal Investigators in breakthrough sprint sessions on a clinical evidence plan and trial design for a renal failure interventional trial.
- Continued deployment of devices for the AstraZeneca trials, both in the US and internationally.

# **Corporate Governance**

ImpediMed's Corporate Governance Statement (Statement) was approved by the Board on 24 August 2021 and can be found at https://investors.impedimed.com/about/corporate-governance/.

Our governance policies and practices have been largely consistent with the 4th edition of the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations throughout the year, with exceptions outlined in our Statement. Our governance policies and practices are reflected in this Statement as well as our Appendix 4G.

# Environmental, Social and Governance (ESG) Reporting

ImpediMed's initiatives to incorporate environmental, social, and governance criteria into our operating framework reflect our commitment to our customers, patients, partners, shareholders, and employees and the communities in which we operate. At ImpediMed, we believe that a focus on ESG is a continuous process of aligning our operations and controls with our company values.

At the core of this framework is strong governance and a robust risk and compliance framework. This framework is supported by procedures and systems to ensure that we apply, at all times, high levels of personal and professional integrity.

# **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.

Donald Williams Chairman Judith Downes Director

25 February 2022



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 the half-year financial report of ImpediMed Limited for the half-year ended 31 December 2021, 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;
- b. No contraventions of any applicable code of professional conduct in relation to the review; and
- c. No non-audit services provided that contravene 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

25 February 2022

# Financial Statements

**CHAPTER 3** 



# CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

For the Half-Year Ended 31 December

	Notes	2021 \$000	2020 \$000
Continuing Operations			
SOZO® Revenue	4	4,858	3,267
Legacy Revenue	4	305	280
Other Revenue	4	33	32
Total Revenue from Contracts with Customers		5,196	3,579
Cost of Goods Sold		(787)	(790)
Gross Profit		4,409	2,789
Other Income	6	812	1,540
Finance Income, net	6	(7)	(16)
Salaries and Benefits	7	(7,784)	(8,528)
Share-based Payments	12	(1,630)	(1,590)
Consulting and Professional Fees	7	(818)	(1,387)
Administrative and Governance Fees	7	(1,409)	(981)
Clinical Trials and Research & Development	7	(251)	(819)
Other Expenses	7	(2,223)	(1,446)
Loss from Operations Before Income Tax		(8,901)	(10,438)
Income Tax		(19)	-
Net Loss		(8,920)	(10,438)
Other Comprehensive Income			
tems that may be reclassified as profit:			
Foreign Currency Translation Gain / (Loss)		392	(1,175)
Other Comprehensive Gain / (Loss) for the Period, Net of Tax		392	(1,175)
Total Comprehensive Loss		(8,528)	(11,613)
		\$	\$
Basic and Diluted Loss per Share	2	(0.01)	(0.01)

The above Consolidated Statement of Comprehensive Income should be read in conjunction with the accompanying notes.

# **CONSOLIDATED BALANCE SHEET**

	Notes	As at 31 Dec 2021 \$000	As at 30 Jun 2021 \$000
Assets			
Current Assets			
Cash and Cash Equivalents	8	50,807	19,681
Trade and Other Receivables	9	2,894	3,705
Contract Assets		1,073	895
Inventories		1,118	372
Prepayments and Other		1,368	997
Total Current Assets		57,260	25,650
Non-Current Assets			
Other Financial Assets		75	73
Right of Use Asset		303	447
Property and Equipment		869	583
Intangible Assets	10	8,982	7,452
Total Non-Current Assets		10,229	8,555
Total Assets		67,489	34,205
Liabilities			
Current Liabilities			
Trade and Other Payables		2,508	1,748
Contract Liabilities		974	877
Provisions		4,515	5,194
Interest Bearing Lease Liabilities		304	315
Total Current Liabilities		8,301	8,134
Non-Current Liabilities			
Contract Liabilities		99	218
Interest Bearing Lease Liabilities		18	159
Provisions		160	180
Total Non-Current Liabilities		277	557
Total Liabilities		8,578	8,691
Net Assets		58,911	25,514
Equity			
Issued Capital	11	307,563	267,268
Reserves		31,035	29,013
Accumulated Losses		(279,687)	(270,767)
Total Equity		58,911	25,514

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	2021	2020
		\$000	\$000
Cash Flows from Operating Activities			
Receipts from Customers (Inclusive of GST and US Sales Tax)		5,069	3,320
Payments to Suppliers (Inclusive of GST and US Sales Tax)		(4,452)	(5,814)
Payments to Employees		(8,698)	(7,057)
Interest Received		8	15
Other Receipts		1,791	2,902
Net Cash Flows Used in Operating Activities		(6,282)	(6,634)
Cash Flow from Investing Activities			
Purchase of Property and Equipment		(27)	(40)
Development Expenditures and Purchase of Intangibles		(2,850)	(934)
Net Cash Flows Used in Investing Activities		(2,877)	(974)
Cash Flows from Financing Activities			
Proceeds from Issue of Ordinary Shares	11	42,503	8,011
Transaction Costs from Capital Raising	11	(2,200)	(72)
Proceeds from borrowings		-	170
Payment of Lease Liabilities		(351)	(224)
Net Cash Flows from Financing Activities		39,952	7,885
5			
Net Increase in Cash and Cash Equivalents		30,793	277
Net Foreign Exchange Differences		333	(919
Cash and Cash Equivalents at Beginning of Period		19,681	19,663
Cash and Cash Equivalents at End of Period	8	50,807	19,02

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 July 2020		250,563	21,117	5,742	26,859	(250,061)	27,361
Loss for the Period from Continuing Operations		-	1	-	1	(10,438)	(10,438)
Other Comprehensive Gain from Continuing Operations		-	-	(1,175)	(1,175)	-	(1,175)
Total Comprehensive Gain / (Loss) for the Period		-	1	(1,175)	(1,175)	(10,438)	(11,613)
Equity Transactions: Share-based Payments Allotment of Ordinary Shares Costs of Capital Raising	12 11 11	- 7,916 (94)	1,590 - -		1,590 - -		1,590 7,916 (94)
At 31 December 2020		258,385	22,707	4,567	27,274	(260,499)	25,160
At 1 July 2021		267,268	24,152	4,861	29,013	(270,767)	25,514
Loss for the Period from Continuing Operations		-	-	-	-	(8,920)	(8,920)
Other Comprehensive Gain from Continuing Operations		-	-	392	392	-	392
Total Comprehensive Loss for the Period		-	1	392	392	(8,920)	(8,528)
Equity Transactions: Share-based Payments Allotment of Ordinary Shares Costs of Capital Raising	12 11 11	- 42,503 (2,208)	1,630 - -		1,630 - -		1,630 42,503 (2,208)
At 31 December 2021		307,563	25,782	5,253	31,035	(279,687)	58,911
The above Consolidated Statement	of Chang	es in Equity	should be re	ead in conju	nction with	the accompanyi	ng notes.

# **NOTES TO THE FINANCIAL STATEMENTS**

FOR THE HALF-YEAR ENDED 31 DECEMBER 2021

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# 1. Basis of Preparation

### **Corporate Information**

The consolidated financial statements of ImpediMed Limited for the six-months ended 31 December 2021 were authorised for issue in accordance with a resolution of the Board of Directors on 25 February 2022.

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 2021 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 2021 and considered together with any public announcements made by the Group during the half-year ended 31 December 2021 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.

### 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 \$50.8 million at 31 December 2021 (30 June 2021: \$19.7 million) and no borrowing from banks or other financial institutions at that date. The Group incurred a total comprehensive loss of \$8.5 million for the half-year ended 31 December 2021 (31 December 2020: \$11.6 million), which included various non-cash items. The Group had \$6.3 million (31 December 2020: \$6.6 million) of net cash outflows from operations.

During the period the Group successfully completed a capital raise of \$42.5 million.

Whilst the Group continues to generate operating losses and net cash outflows from operations, the Group's future viability is dependent upon managing existing cash balances, and achieving increased cash inflows from cash receipts from customers.

The Directors are confident the Group will be able manage cashflows and 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 and thus continue as a going concern.

On this basis, the going concern basis of accounting has been used.

### 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 2021 \$000	31 Dec 2020 \$000
Net Loss Used in Calculating Basic and Diluted Earnings Continuing Operations	(8,920)	(10,438)
Net Loss Attributable to Ordinary Equity Holders of the Parent for Basic and Diluted Earnings per Share	(8,920)	(10,438)
	No.	No.
Weighted Average Number of Ordinary Shares Used in Calculating Basic and Diluted Earnings per Share	1,582,613,351	1,053,046,050
	\$	\$
Basic and Diluted Loss per Share	(0.01)	(0.01)
Basic and Diluted Loss per Share from Continuing Operations	(0.01)	(0.01)

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 convertible instruments. For the financial half-year ended 31 December 2021, 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 84,730,423 (31 December 2020: 61,583,501) options and 45,963,845 (31 December 2020: 25,980,345) 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

### Medical Segment

During the half-year, the Chief Executive Officer (whom is the Chief Operating Decision Maker) 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.

The Medical segment is a supplier of non-invasive medical equipment of software employing 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 commercialisation of SOZO, which is focused on building a high margin contracted revenue pipeline for strong recurring revenue growth. Refer to the 2021 Annual Report for additional information on the Group's segment reporting.

# Inter-Company Transactions

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

### Segment Results

The following table presents revenue and profit information for reportable segments for the six-months ended 31 December 2021 and 2020:

At 31 December 2021	Medical					
	SOZO – Core Business \$000	SOZO – Clinical Business \$000	Total SOZO \$000	Legacy \$000	Other \$000	Total \$000
Revenue	-	-				
Recurring Subscription and Consumable Revenue from Contracts with Customers	2,628	1,484	4,112	130	-	4,242
Recurring Device Revenue from Leases	-	162	162	-	-	162
Device Revenue from Contracts with Customers	584	-	584	175	-	759
Other Revenue	-	-	-	-	33	33
Total Revenue	3,212	1,646	4,858	305	33	5,196
Cost of Revenue						
Cost of Recurring Subscription and Consumable Revenue from Contracts with Customers			(131)	(15)		(146)
Cost of Recurring Device Revenue from Leases			(126)	-	-	(126)
Cost of Device Revenue from Contracts with Customers			(286)	(70)	-	(356)
Cost of Other Revenue			-	-	(159)	(159)
Total Cost of Revenue			(543)	(85)	(159)	(787)
Gross Margin						
Gross Margin – Recurring Subscriptions and Consumables			3,981	115	-	4,096
Gross Margin – Recurring Devices			36	-	-	36
Gross Margin - Devices			298	105	-	403
Gross Margin - Other Revenue			-	-	(126)	(126)
Blended Margin			4,315	220	(126)	4,409
Gross Margin %						
Gross Margin – Recurring Subscriptions and Consumables			97%	88%	-	97%
Gross Margin – Recurring Devices (i)			22%	-	-	22%
Gross Margin - Devices			51%	60%	-	53%
Blended Margin %			89%	72%		85%

<sup>(</sup>i) Gross Margin – Recurring Devices relates to the accounting treatment for revenue recognised on devices within the Clinical Business. The majority of revenue under these contracts is recognised as high-margin subscription revenue.

At 31 December 2020	Medical					
	SOZO - Core Business \$000	SOZO - Clinical Business \$000	Total SOZO \$000	Legacy \$000	Other \$000	Total \$000
Revenue						
Recurring Subscription and Consumable Revenue from Contracts with Customers	1,977	370	2,347	191	-	2,538
Recurring Device Revenue from Leases	-	-	-	-	-	-
Device Revenue from Contracts with Customers	920	-	920	89	-	1,009
Other Revenue	-	-	-	-	32	32
Total Revenue	2,897	370	3,267	280	32	3,579
Cost of Revenue						
Cost of Recurring Subscription and Consumable Revenue from Contracts with Customers			(143)	(17)	-	(160)
Cost of Recurring Device Revenue from Leases			-	-	-	-
Cost of Device Revenue from Contracts with Customers			(335)	(28)	-	(363)
Cost of Other Revenue			-	-	(267)	(267)
Total Cost of Revenue			(478)	(45)	(267)	(790)
Gross Margin  Gross Margin – Recurring  Subscriptions and Consumables			2,204	174	-	2,378
Gross Margin – Recurring Devices			-	-	-	-
Gross Margin - Devices			585	61	-	646
Gross Margin - Other Revenue			-	-	(235)	(235)
Blended Margin			2,789	235	(235)	2,789
Gross Margin %						
Gross Margin – Recurring Subscriptions and Consumables			94%	91%	-	94%
Gross Margin – Recurring Devices			-	-	-	-
Gross Margin - Devices			64%	69%	-	64%
Blended Margin %			85%	84%		78%

### Segment Revenue

SOZO revenue increased to \$4.9 million for the six-months ended 31 December 2021, an increase of 49% over the prior period.

SOZO Software as a Service (SaaS) Gross Margins have steadily increased to 97% thus far through the six-months ending 31 December 2021 (31 December 2020: 94%). The Group anticipates SaaS gross margins will be in excess of 94% for the remainder of this financial year, with these margins likely to remain above 90% thereafter.

### **Geographical Segments**

The following tables present SOZO revenue based on geographical segments for the six-months ended 31 December 2021 and 2020. 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.

### Clinical Business

The Clinical Business refers to revenue generating contracts related to clinical trials. These contracts are often finite in nature, as they relate to clinical trials with specific end dates. The Group does not manage the Clinical Business based on geographical locations.

# Geographical Segment Revenue

At 31 December 2021	Australia/ROW \$000	North America \$000	Total \$000
Revenue from Subscriptions and Consumables	206	2,551	2,757
Revenue from Devices	404	356	760
Other Revenue	19	14	33
Total Segment Revenue	629	2,921	3,550
Unallocated Revenue (i)			1,646
Total Consolidated Revenue			5,196

At 31 December 2020	Australia/ROW	North America	Total
	\$000	\$000	\$000
Revenue from Subscriptions and Consumables	211	1,957	2,168
Revenue from Devices	442	567	1,009
Other Revenue	11	21	32
Total Segment Revenue	664	2,545	3,209
Unallocated Revenue (i)			370
Total Consolidated Revenue			3,579

<sup>(</sup>i) Unallocated revenue primarily consists of revenue derived from the Clinical Business, which is not allocated to a specific geography.

### Segment Assets

All segment assets relating to the Group's operating segments as at 31 December 2021 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.

During the period the group continued to recognise revenue from a number of agreements with customers within the Clinical Business. These agreements involve leasing SOZO devices for a finite period of time with use of subscription services over that period. These agreements contain both a lease component, being the individual SOZO devices delivered to the Customer, and a non-lease component, being the software subscription service provided to the Customer. Based on the structure of these agreements, the lease of devices is accounted for in accordance with AASB as an operating lease and the license to software is accounted for in accordance with AASB15.

Refer to Note 4 for a breakdown of revenue by operating and geographical segments.

# 6. Finance and Other Income

Other Income	31 Dec 2021	31 Dec 2020
	\$000	\$000
R&D Tax Incentive (i)	812	949
Proceeds from Tax Refunds, Grants, and Other (ii)	-	591
Total Other Income	812	1,540

<sup>(</sup>i) 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.

(ii) In the prior period, the Group received various government grants, which were primarily related to COVID-19 economic stimulus programs.

Finance Income, Net	31 Dec 2021	31 Dec 2020
	\$000	\$000
Interest Income – term deposits	10	15
Interest Expense – lease liability	(17)	(31)
Total Finance Income, Net	(7)	(16)

# 7. Expenses

Salaries and Benefits	31 Dec 2021 \$000	31 Dec 2020 \$000
Wages and Salaries (i)	6,141	5,420
Short-term Incentives and Sales Commissions (ii)	1,152	2,714
Employee Benefits and other costs	1,107	1,061
Superannuation	250	232
Capitalised Employee Costs (i)	(866)	(899)
Total Salaries and Benefits	7,784	8,528

- Certain Wages and Salaries relating to SOZO software development have been recognised as Intangible Assets in accordance with AASB 138 Intangible Assets in both the current and prior corresponding periods. In addition, certain wages and salaries directly related to SOZO customer installations and trainings are allocated to cost of revenue for the current prior corresponding periods.
- In the prior period, the Group achieved above-plan performance for short term incentives, resulting in a greater expense compared to the current

Research and Clinical Trials	31 Dec 2021 \$000	31 Dec 2020 \$000
Oncology Clinical Trials (i)	64	705
Cardiology and Other Clinical Trials	183	107
Product Engineering and other Research and Development	4	7
Total Research and Clinical Trials	251	819

The decrease in oncology clinical trials related to the completion of the PREVENT trial.

Insurance (i) Governance and Regulatory Fees	\$000 646	\$00
Governance and Regulatory Fees	646	Ş00
· ·		50
Administrative Evanges	396	28
Administrative Expenses	210	13
Directors' Fees (ii)	151	2
Foreign Currency Loss on Transactions	6	2
Total Administrative and Governance Fees	1,409	98
Consulting and Professional Fees		
Consulting and Professional Fees	31 Dec 2021	31 Dec 202
	\$000	\$00
Consulting Fees (i)	516	98
Patent and Trademark Fees	211	32
Professional Fees	91	
Total Consulting and Professional Fees	818	1,3

- Consistent with movements across the industry, The Group saw an increase in insurance premiums in the current period.
- In the prior period, 100% of board fees were received as shares in lieu of cash. During the current period, Directors began receiving a portion of their fees as cash in order to cover tax obligations associated with their share issuances.

Consulting and Professional Fees	31 Dec 2021 \$000	31 Dec 2020 \$000
Consulting Fees (i)	516	982
Patent and Trademark Fees	211	326
Professional Fees	91	79
Total Consulting and Professional Fees	818	1,387

Other Expenses	31 Dec 2021	31 Dec 2020
	\$000	\$000
Depreciation and Amortisation (i)	1,103	842
T, Property and Other Expenses (ii)	464	339
Advertising and Promotion (iii)	315	160
Travel Expenses (iv)	184	67
Other (v)	157	38
Total Other Expenses	2,223	1,446

- The increase in Depreciation and Amortisation expense in the current period was primarily attributable to software development and other enhancements.
- IT expenses in the current period increased due to increased software license fees related to improving reporting capabilities related to SOZO.
- (iii) Advertising and promotion expenses increased in the current period as a result of continued investment in the Lymphoedema Prevention Program
- Travel expenses increased in the current period as there were less restrictions compared to the prior year related to COVID-19.
- Other expenses primarily increased due to warranty costs in the current period. (v)

# 8. Cash and Cash Equivalents

	As at 31 Dec 2021 \$000	As at 30 Jun 2021 \$000
Cash at Bank and in Hand	21,754	8,182
Short-term Deposits	29,053	11,499
Cash and Cash Equivalents	50,807	19,681

	As at 31 Dec 2021 \$000	As at 30 Jun 2021 \$000
Trade Receivables	1,912	1,964
Allowance for Expected Credit losses	(28)	(84)
Tax, Interest, and Other Receivables	1,010	1,825
Total Trade and Other Receivables	2,894	3,705

Trade and Other Receivables		
	As at 31 Dec 2021	As at 30 Jun
	\$000	
Trade Receivables	1,912	
Allowance for Expected Credit losses	(28)	
Tax, Interest, and Other Receivables	1,010	
Total Trade and Other Receivables	2,894	
Allowance for Expected Credit losses	2021	
J)	\$000	
At 1 July	(84)	
Charge for the Period	(16)	
Amounts Reversed	39	
Amounts Written Off	35	
Foreign Exchange Translation	(2)	
gorongin =xonianigo in anionation		

### Fair Value and Credit Risk

Due to the short-term nature of these receivables, the carrying value is assumed to approximate its fair value. The maximum exposure to credit risk is the fair value of the receivables.

Trade receivables, which generally have 30-90 day terms, are recognised at fair value less an expected credit loss for impairment.

Collectability of trade receivables is reviewed on an ongoing basis at an operating unit level. Individual debts that are known to be uncollectable are written off when identified. An impairment provision is recognised when there is objective evidence that the Group will not be able to collect the receivable. Financial difficulties of the debtor, default payments or debts more than 90 days overdue are generally considered objective evidence of impairment.

The maximum exposure to credit risk at the reporting date is the higher of the carrying value or fair value of each class of receivables. No collateral is held as security.

When financial assets are recognised initially, they are measured at fair value plus, in the case of assets not at fair value through profit or loss, directly attributable transaction costs.

# Non-Current Assets – Intangible Assets and Goodwill

### Intangible Assets

Intangible assets, including goodwill, totaled \$9.0 million at 31 December 2021 (30 June 2021: \$7.5 million).

During the six months ended 31 December 2021, the Group generated intangible assets with a cost of \$2.4 million (31 December 2020: \$0.9 million), which consisted of \$1.4 million of SOZO II development and \$1.0 million of recurring software development costs. The Group anticipates SOZO II project costs will be completed in early FY23. 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 \$2.5 and \$2.4 million at 31 December 2021 and 30 June 2021, respectively, with the movement relating to foreign exchange translation.

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 2021, the Group found no evidence of indicators of impairment of goodwill or other assets, and as a result, no impairment test has been performed at the reporting date.

# 11. Issued Capital

# **Ordinary Shares**

	Number of Shares	\$000
At 31 December 2020	1,076,596,070	258,385
Issued During the Period as a Result of:		
Issue of Ordinary Shares from Capital Raisings (i)	411,374,799	8,923
Issue of Non-Executive Director and Employee Share Plans	3,707,669	-
Issue of Employee Share Based Payments	-	-
Transaction Costs	-	(40)
At 30 June 2021	1,491,678,538	267,268
Issued During the Period as a Result of:		
Issue of Ordinary Shares from Capital Raisings (ii)	278,688,274	42,503
Issue of Non-Executive Director and Employee Share Plans	5,268,190	-
Issue of Employee Share Based Payments	177,500	-
Transaction Costs	-	(2,208)
At 31 December 2021	1,775,812,502	307,563

<sup>(</sup>i) In total, the Group received \$17.9 million in option exercises related to the 2 April 2020 Entitlement Offer at \$0.0375 per share, of which \$8.9 million was received during the period.

# 12. Share-Based Payments

		31 Dec 2021 \$000	31 Dec 2020 \$000
1	Share-Based Payments to Employees	1,469	1,363
1	Share-Based Payments to Non-Executive Directors share plan	161	227
	Total Share-Based Payments	1,630	1,590

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

The Group continued an Executive Share Plan whereby up to 20% of an Executive's gross salary and short-term incentives were taken as shares in lieu of cash. During the six months ended 31 December 2021, the Non-Executive Share Plan was amended to have 60% of Directors' Fees taken as shares in lieu of cash and 40% of Director's fees paid in 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 2021 AGM Notice for full details of the plans.

During the period, share-based payments issued under the Executive Share Plan to Executives were approximately \$362,000 (31 December 2020: 341,000).

<sup>(</sup>ii) The Group completed a capital raise during the period which for \$42.5 million in gross proceeds at \$0.1525 per share. The capital raise consisted of a \$35 million Placement to new and existing institutional and sophisticated investors, as well as a \$7.5 million Share Placement Plan to existing eligible shareholders.

### **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 an appropriate valuation methodology (either Black Scholes model or Monte Carlo Simulation), taking into account the terms and conditions upon which the options were granted.

The weighted average fair value of options granted during the six-month period was \$0.11 (31 December 2020: \$0.05).

# 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.

### Awards during the Period

During the current period, 30,254,000 share options (31 December 2020: 29,228,000) and 20,603,000 performance rights (31 December 2020: 20,011,000) were granted under the EIP. The awards granted included 14,491,000 share options (31 December 2020: 15,677,000) and 14,855,000 performance rights (31 December 2020: 15,980,000) 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 (%)	81.00	N/A
Risk-Free Rate of Return (%)	0.83	N/A
Dividend Yield (%)	-	-
Average Expected Life (years)	4.89	3.00
Strike Price (\$)	0.177	-

# 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	
		31 Dec 2021	31 Dec 2020
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 2021, 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 2021, the Group has commitments of \$0.8 million (30 June 2021: \$1.8 million) relating to the funding of future product builds, clinical trials, advertising and promotional activities, and other activities. The majority of the expenditure commitments relate to SOZO product builds to meet increasing demands for SOZO devices.

# Contingent Liabilities

The Group had no contingent liabilities as at 31 December 2021.

# 15. Events After the Balance Sheet Date

# Issuance of Ordinary Shares - Equity Share Plans

On 6 January 2022, the Group issued 1,083,112 shares to Non-Executive Directors and Executives as part of the Equity Share Plans, related to the Q2 FY'22 performance period covering 1 October 2021 – 31 December 2021. These shares were issued in lieu of cash remuneration, which comprised 60% of Directors' fees and up to 20% of Executives' base salaries.

### PREVENT Trial Peer Reviewed and Published

The Group announced that the PREVENT trial results have been peer-reviewed and published in *Lymphatic Research and Biology*, a journal dedicated to research on lymphatic biology and pathology from the world's leading biomedical investigators.

### Clinical Trial Agreement announced for the SOZO Platform in Patients with End Stage Renal Disease (ESRD)

The Group announced it has entered into an agreement with balboa RESEARCH SMO+ and Frenova Renal Research, a Fresenius Medical Care company, to conduct an initial Observational Trial. Dr Mark Boiskin and Dr Dylan Steer have agreed to serve as Principal Investigators for both the Observational Trial and a pivotal Interventional Trial, which will be used to support an application for FDA clearance for use of the device for patients with ESRD.

# New Bone Data Comparing ImpediMed's SOZO to DXA in Cancer Patients to be Presented at 39th Annual Miami Breast Cancer Conference

The Group announced that an abstract comparing concurrent measures using ImpediMed's SOZO Digital Health Platform and dual x-ray absorptiometry (DXA) for assessing bone mineral content in cancer patients was accepted for poster presentation at the 39th Annual Miami Breast Cancer Conference on 3-6 March 2022 in Miami Beach, Florida, USA. The abstract titled "The Routine Use of Bioimpedance Spectroscopy Measurements in the Clinic as a Surrogate for Bone Mineral Content in Oncology Patients: Practical Application of the SOZO Device" analyses data collected using both SOZO and DXA in healthy participants and cancer patients.

# **Directors' Declaration**

For the half-year ended 31 December 2021

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 2021 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 2021 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.
  - (b) 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

on Williamo

Donald Williams Chairman Judith Downes Director

25 February 2022



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

# Independent auditor's review report to the members of ImpediMed Limited

### Conclusion

We have reviewed the accompanying half-year financial report of ImpediMed Limited (the Company) and its subsidiaries (collectively the Group), which comprises the consolidated balance sheet as at 31 December 2021, the consolidated statement of comprehensive income, consolidated statement of changes in equity and statement of cash flows for the half-year ended on that date, notes comprising a description of 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 the Group does not comply with the *Corporations Act* 2001, including:

- a. Giving a true and fair view of the consolidated financial position of the Group as at 31 December 2021 and of its consolidated financial performance for the half-year ended on that date; and
- b. Complying with Accounting Standard AASB 134 Interim Financial Reporting and the Corporations Regulations 2001.

### Basis for conclusion

We conducted our review in accordance with ASRE 2410 Review of a Financial Report Performed by the Independent Auditor of the Entity (ASRE 2410). Our responsibilities are further described in the Auditor's responsibilities for the review of the half-year financial report section of our report. We are independent of the Group in accordance with the auditor independence requirements of the Corporations Act 2001 and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 Code of Ethics for Professional Accountants (including Independence Standards) (the Code) that are relevant to our audit of the annual financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

# Directors' responsibilities 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.

# 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. ASRE 2410 requires us to conclude whether we have become aware of any matter that makes us 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 financial position as at 31 December 2021 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*.



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.

Ernst & Young

Ernst & Young

Jennifer Barker Partner

Brisbane

25 February 2022

Platform Technology. Transforming Care.

# Interim Financial Report