

30 November 2023

## ASX ANNOUNCEMENT

### 2023 Annual General Meeting – Chair’s Address and Presentation

ImpediMed Limited (ASX:IPD) (**ImpediMed** or **Company**) provides the attached Chair’s Address and Presentation to be delivered at today’s Annual General Meeting commencing at 11.00am AEDT at the offices of Clifford Chance Level 24, Brookfield Place, 10 Carrington Street, Sydney NSW 2000 and online at [meetings.linkgroup.com/IPD23](https://meetings.linkgroup.com/IPD23).

**Approved for release by the Board of the Company.**

#### Contact Details

**Investor Relations Contact:**

Hannah Howlett

WE Communications

T: +61 450 648 064

E: [hhowlett@we-worldwide.com](mailto:hhowlett@we-worldwide.com)

E: [investorrelations@impedimed.com](mailto:investorrelations@impedimed.com)

#### About ImpediMed

Founded and headquartered in Brisbane, Australia with US and European operations, ImpediMed is a medical technology company that uses bioimpedance spectroscopy (BIS) technology to generate powerful data to maximise patient health. ImpediMed produces the SOZO® Digital Health Platform, which is FDA-cleared, CE-marked, and ARTG-listed for multiple indications, including lymphoedema, heart failure, and protein calorie malnutrition and sold in select markets globally.

In March 2023, the NCCN Clinical Practice Guidelines In Oncology (NCCN Guidelines®) for Survivorship were updated and reference bioimpedance spectroscopy as the recommended objective tool to screen at-risk cancer patients for early signs of lymphoedema. With the SOZO Digital Health Platform and L-Dex®, ImpediMed is the only company to offer FDA-cleared technology that uses bioimpedance spectroscopy for the clinical assessment of lymphoedema. The connected digital health platform and large, attractive cancer-related lymphoedema market present an opportunity for continued strong growth through ImpediMed’s SaaS subscription-based business.

For more information, visit [www.impedimed.com](https://www.impedimed.com).

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### **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.

## Impedimed Limited – 2023 Annual General Meeting Chair's Address – Mr McGregor Grant

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As I am sure you are aware, there have been a lot of changes at Impedimed over the last 18 months including, most recently, the departure of the CEO and the CFO, announced last week. Accordingly, there will be no CEO presentation at this AGM. However, as part of my address, I will provide an overview of Impedimed's operations and achievements during the 2023 financial year.

I would like to take this opportunity to provide some context to the recent changes and why I believe they put the Company in a stronger position to capitalise on the compelling commercial opportunity that SOZO and our unique bioimpedance technology offers.

At the General Meeting held on 28 September this year, Impedimed's shareholders voted in favour of replacing four of the Company's Directors with new Directors. Subsequent to that vote, the remaining two Non-Executive Directors, who were part of Impedimed's previous Board, have resigned. As a result, Impedimed's Board currently comprises the four Directors who were elected at the General Meeting.

I think it is important to recognise that many of Impedimed's shareholders felt it was necessary to make changes at the Board level. In July this year, the Company received a notice from a number of experienced long-term private shareholders requesting the Company call a General Meeting to consider a proposal to remove and replace four of the Directors. While I do not intend to go through a detailed description of all the events leading up to the September General Meeting, the result of the meeting confirmed there was strong support for change.

I would also like to comment on the recently announced departure of CEO Rick Valencia and CFO Tim Cruickshank. As mentioned in the ASX announcement, having taken into consideration the strength and capabilities of Impedimed's core management team and the need to deliver robust execution combined with tighter fiscal management, the Board determined new leadership was required to drive towards profitable growth and maximise the Company's long-term potential.

I have assumed the role of CFO, initially on an interim basis and will be working with Tim over the next couple of months to ensure an orderly transition. For those who do not know, I was CFO for 12 years at the ASX-listed company Nanosonics, and during my time with the business, annual revenue grew from \$2 million to \$166 million. Like Impedimed, Nanosonics' business model is based on generating revenue through the initial sale of capital equipment into healthcare settings, and then generating annuity revenue from the use of that capital equipment. So, this is something I have been living and breathing for the last 12 years.

It is also with delight that we announced the appointment of Dr Parmjot Bains as Managing Director and CEO, again, initially on an interim basis. As well as being a medical doctor, Dr Bains has an impeccable track record of setting and executing on commercial strategy, aligning team capabilities, driving private and public reimbursement, management of key accounts, implementing marketing programs and accelerating sales. Most recently, Parmjot was a senior executive at Pfizer where she had several roles across the US, Asia, the Middle East and Australia. Prior to this, Dr Bains held CEO roles at two life science companies and

was a manager at the consulting firm McKinsey & Company. The Board believes Parmjot's breadth of experience across all of these areas will be invaluable in capitalising on the opportunity available for SOZO in the United States, following the recent inclusion of bioimpedance spectroscopy in the NCCN guidelines and the subsequent nationwide expansion of private payor coverage.

I would also like to emphasise the Board believes, in our respective roles of CEO and CFO, Dr Bains and I have the experience, capabilities and passion to drive commercial outcomes, provide strong discipline over expenditure and ensure strong corporate governance. Importantly, we are firmly of the view that our appointment will ensure stability and continuity of the business' operations ensuring we maximise the significant commercial opportunity for SOZO.

It is the Board's intention that the CEO and CFO positions will convert to permanent roles in three to six months' time. However, the Board decided it was prudent to make our initial appointments interim so that in the event they do not work out, for any reason, the Company is not exposed to any ongoing financial obligation associated with the appointment of new executives.

As I mentioned earlier, the Board currently comprises the four recently elected Directors, which will increase to five when Dr Bains joins the Board in early January. The Board has commenced a search process to identify potential Directors to join the Board and expects to announce the appointment of one or two additional directors in the coming months.

I would like to conclude this portion of my address by adding that the last eight weeks have provided the Board with the opportunity to gain a deeper understanding of the potential of this business. As I have previously indicated, there is a very capable core management team and a unique and distinctive product portfolio which combine to create an exceptional commercial opportunity. The Board is excited to be part of the Impedimed story and we look forward to supporting the business with a clear focus on achieving profitable growth.

### **Overview of FY23**

I will now provide an overview of the financial and operational highlights of FY23, which shows why we are so excited by the commercial opportunity provided by this business.

### **FY23 Financials**

A summary of the financial results for FY23 is shown on the slide. The key metrics to note include:

- SOZO revenue in FY23 was \$10.6 million, which was an increase of 7% compared with FY22.
- The net loss before tax for FY23 was \$20.5 million, which compares with a net loss of \$19.8 million in FY22.
- Free cash outflow of \$24.1 million in FY23, compared with free cash outflow of \$20.9 million in FY22.

- As at 30 June the Company was holding cash and cash equivalents of \$45.7 million, compared with \$40.7 million a year earlier. I note in the recent Q1 FY24 Appendix 4C announcement the Company reported cash and cash equivalents of \$42.4 million as at 30 September 2023.

### **Period of changes**

As I mentioned earlier, there have been many changes at Impedimed over the last 18 months including three CEOs and the refreshing of the entire Board. The current Board is fully aware that these changes have been disruptive for the business and there is a need for stability.

With these recent changes, the Board is confident that we now have the right leadership in place and the Company can look forward to a period of stability, allowing the management team to focus on the immediate objective of successfully commercialising the lymphoedema opportunity.

### **Covering all patients at risk of limb lymphoedema**

In March this year, the NCCN guidelines were updated to include bioimpedance spectroscopy, or BIS, as an objective measurement tool to identify early signs of lymphoedema. These guidelines now recommend regular screening for all cancer survivors at risk of lymphoedema, not just breast cancer patients. Most significantly, Impedimed has the only FDA-cleared BIS technology for the assessment of lymphoedema.

Inclusion in the NCCN Guidelines in Oncology for Survivorship will help establish BIS as the standard of care and will accelerate the adoption of Impedimed's technology by Private Payors and Providers.

### **Major milestone with NCCN inclusion**

Inclusion in the NCCN Oncology Survivorship Guidelines also significantly expands the addressable market opportunity beyond breast cancer. There are 1.9 million new cancer diagnoses in the US each year and Breast Cancer Related Lymphoedema represents approximately 300,000 new cancer diagnoses in the US each year or 15% of all cancer diagnoses.

However, based on the inclusion of BIS in the Cancer Survivorship guidelines, Impedimed's SOZO technology is relevant for over 1.1 million new cancer diagnoses in the US each year which equates to approximately 58% of all cancer diagnoses. These 1.1 million cancer patients are treated at over 5,600 inpatient and outpatient facilities across the United States.

### **Private payor coverage gaining momentum**

In the recent Appendix 4C quarterly activities report, the Company confirmed:

- 12 positive medical policies had been published since inclusion of SOZO® and BIS in the NCCN Guidelines®, including Top 5 National Payor, Cigna Healthcare and seven Blue Cross Blue Shield policies;
- There were 3 confirmed Regional medical policy revisions pending publication; and

- 27 Payors were providing silent coverage for CPT code 93702.

Significantly, on 3 November 2023 the Company announced that UnitedHealthcare, the largest Private Payor in the US, had amended its policy to state that CPT code 93702 no longer required clinical review effective from 1 January 2024 - i.e. they will provide silent coverage.

During FY23 Michigan achieved Critical Mass with over 97% of lives covered. Michigan is a key market with strong reimbursement rates. In Q1 FY24 the Company signed a Master Services Agreement with a large Michigan IDN, representing over 20 hospital systems.

In this quarter, the Company expects an additional 3-6 states will achieve Critical Mass. A number of these states are considered to be key markets.

### **Increase in follow-up patient testing**

In addition to securing expanded reimbursement coverage from Private Payors, we are also starting to see some momentum around patient testing.

In November 2022, the Company reported that the 500,000<sup>th</sup> patient assessment using SOZO had been conducted. By the time of the annual report, this number had increased to 650,000 assessments.

While we have yet to see a significant acceleration in the rate of testing since the announcement of the NCCN guideline inclusion, we do expect this to occur over time due to:

- The greater number of eligible patients under the Survivorship guidelines; and
- Greater reimbursement coverage leading to greater adoption of routine monitoring.

The number of new patients, indicated in dark blue on the bars, provides a useful lead indicator of future testing as they transition into routine follow-up and monitoring programs.

### **Sale of SOZO systems**

It is useful to review the Company's progress in terms of the number of SOZO systems sold.

Since the launch of SOZO, a total of approximately 500 SOZO units have been sold in the US and approximately a further 500 units sold in markets outside the US, predominantly in Australia.

During FY23 a total of 78 SOZO systems were sold in the US, including 34 systems sold in Q4 FY23. Recently we reported that an additional 19 units were sold in the US in Q1 FY24.

### **Other achievements in FY23**

It is important to recognise a number of other achievements in FY23. These include:

- Obtaining FDA clearance for SOZO Pro, which is expected to be launched in CY24. I note the FDA clearance was recently modified to remove the contraindications for implantable pacing and cardioverter defibrillator devices;

- Extending the clinical trial contract with Astra Zeneca. I also note revenue under this contract ended in Q1 FY24; and
- Raising a total of \$30 million in capital via a \$20 million institutional placement announced in May 2023, and \$10 million via an oversubscribed Share Purchase Plan announced in June.

### **Outlook For FY24 and beyond**

Turning to the outlook for FY24 and beyond.

The key focus is to drive Impedimed towards profitable growth:

- There is a compelling opportunity with guidelines and expanding private payor coverage;
- There will be an increased internal focus on execution to achieve robust sales and commercial outcomes; and importantly
- We will seek to achieve growth with an appropriate cost structure and cost controls.

The organisation is in place to achieve profitable growth:

- We have a very capable and motivated core management team;
- We have a distinctive product portfolio with an undeniable commercial opportunity; and
- We have a new Board completely aligned with interests of its shareholders.

Finally, we have experienced new leadership focused on driving towards profitable growth.

Thank you.

## Summary of FY23 financial results

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- SOZO® revenue of \$10.6 million — up 7% from FY22
- Total revenue of \$11.3 million — up 7% from FY22
- Gross margin of 86% — up from 84% in FY22
- Net loss of \$20.5 million — vs loss of \$19.8 million in FY22
- Free cash outflow of \$24.1 million — vs Free cash outflow of \$20.9 million in FY22
- Financing cash inflow of \$27.9 million — vs inflow of \$39.9 million in FY22
- Closing cash balance of \$45.7 million — vs closing balance of \$40.7 million in FY22



## Period of many changes at the leadership level

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|      |          |   |
|------|----------|---|
| FY23 | Jul 2022 | CEO Rick Carreon steps down, David Anderson appointed interim CEO                               |
|      | Aug 2022 | Jan West appointed as Non-Executive Director  |
|      | Oct 2022 | Judith Downes resigns as Non-Executive Director   |
|      | Nov 2022 | Reorganisation of roles in C-suite  |
|      | Nov 2022 | Appointment of Richard Valencia as CEO and Managing Director                                    |
|      | Mar 2023 | Australian-based Chief Commercial Officer role made redundant                                   |
|      | Jun 2023 | Daniel Sharp and Dr Michael Seiden appointed to Board, Dr Robert Grahams resigns                |
| FY24 | Sep 2023 | Dr Stephen Chen appointed as Chief Medical Officer  |
|      | Sep 2023 | Shareholders vote to replace four Directors, Jan West resigns from Board                        |
|      | Nov 2023 | Dr Michael Seiden resigns from Board  |
|      | Nov 2023 | CEO Rick Valencia & CFO Tim Cruikshank step down, McGregor Grant and Dr Parmjot Bains appointed |

## Covering all patients at risk of limb lymphoedema

March 2023

**NCCN released new Clinical Practice Guidelines in Oncology for Survivorship.**

- Specifically name bioimpedance spectroscopy (BIS) as an objective measurement tool to identify early signs of lymphoedema
- NCCN Guidelines now recommend regular screening for all cancer survivors at risk of lymphoedema (not just breast cancer patients)
- Impedimed has the only FDA-cleared BIS technology for the assessment of lymphoedema

**Inclusion in the NCCN Guidelines in Oncology for Survivorship:**

- Will help establish BIS as the standard of care
- Accelerate adoption by Private Payors and Providers



National  
Comprehensive  
Cancer  
Network®

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## Major milestone with inclusion in NCCN Guidelines

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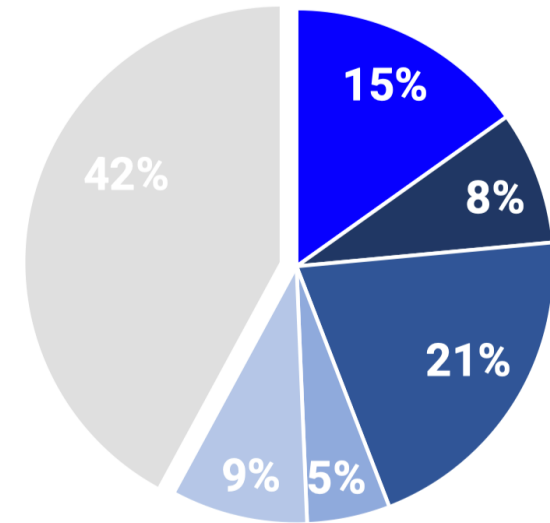
Inclusion in Oncology Survivorship Guidelines significantly expands addressable market opportunity beyond breast cancer

There are 1.9 million new cancer diagnoses in the US each year <sup>1</sup>

The Breast Cancer Related Lymphoedema (BCRL) market represent approximately 300,000 new cancer diagnosis in the US each year (15% of all cancer diagnoses)

Impedimed's current technology is capable of addressing over 1.1 million new cancer diagnoses in the US each year (58% of all cancer diagnoses)

These 1.1 million cancer diagnoses cover over 5,600 facilities (inpatient and outpatient)



■ Breast 290,560

■ Colorectal 160,470

■ Genital 395,600

■ Skin 99,780

■ Urinary 164,190

■ Not at risk of limb lymphoedema 807,430

<sup>1</sup> National Cancer Institute: <https://seer.cancer.gov/statfacts/html/common.html>

## Expansion of Private Payor coverage gaining momentum

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As at 20 October 2023, the status of Private Payor Coverage was as follows:

- 12 positive medical policies published since inclusion of SOZO® and BIS in the NCCN Guidelines® led by Top 5 National Payor Cigna Healthcare and seven Blue Cross Blue Shield policies
- 3 confirmed Regional medical policy revisions pending publication
- 27 Payors providing silent coverage for CPT code 93702

On 3 November 2023 the Company announced that UnitedHealthcare, the largest Private Payor had amended its policy to state that CPT code 93702 no longer required clinical review (i.e. silent coverage)

During FY23 – Michigan achieved Critical Mass (> 80% covered lives):

- 97% covered lives
- Key market with strong reimbursement rates
- Signed Master Services Agreement with large Michigan IDN in Q1 FY2024 representing 20+ hospital systems

Additional 3-6 states expected to achieve Critical Mass in Q2 FY2024

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## Patient Testing Starting to Gain Momentum

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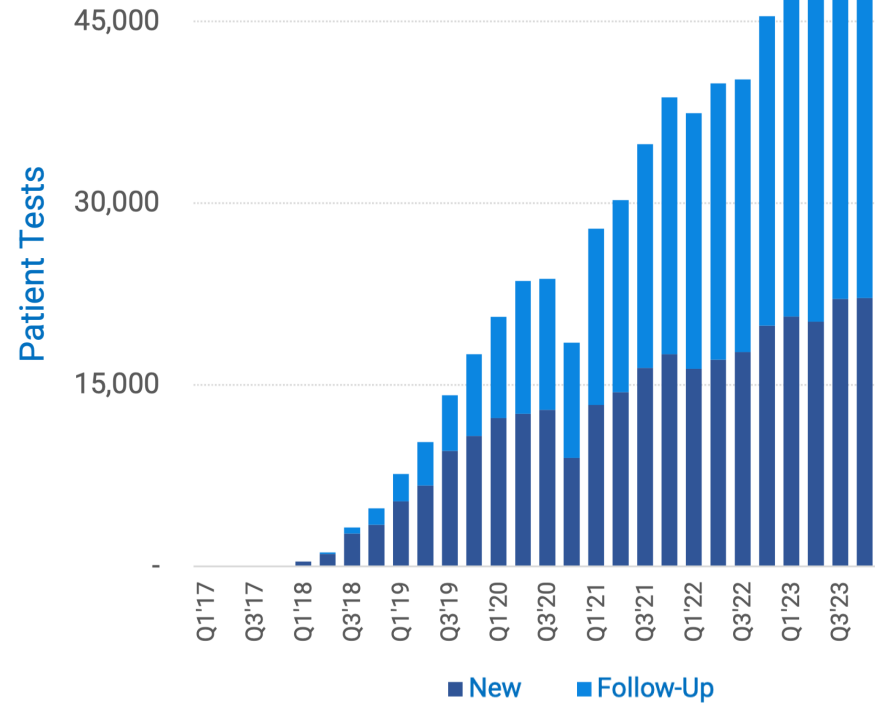
In November 2022, Impedimed reached milestone of 500,000 patient tests performed with SOZO

Since that time, over an additional 150,000 patient tests using SOZO have been conducted taking the total to >650,000

We believe that with the inclusion of BIS in the NCCN Cancer Survivorship guidelines this should accelerate due to:

- Larger pool of cancer patients covered under Survivorship guidelines vs just breast cancer
- Increased coverage by Private Payors should drive increased adoption

SOZO Patient Tests To-Date  
(650,000+ on File)



## Sale of SOZO systems

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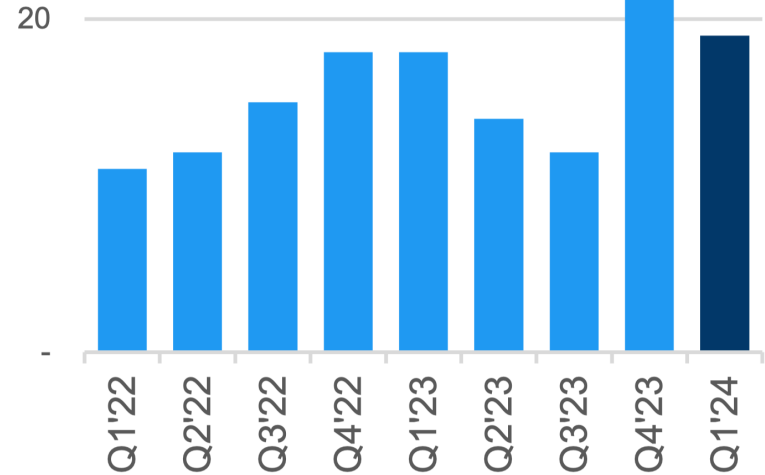
- Total of 500+ SOZO systems sold in the US to date with 1,000+ units sold globally since launch

- Total of 78 SOZO systems sold in the US during FY23 (including 34 systems sold in Q4 FY23). An additional 19 units sold in Q1 FY24

- The contracts that generated \$9.4 million in revenue in FY23 are expected to provide \$11.0 million in revenue in FY24

- Additional upside as new customers and contracts on-boarded following updates to guidelines and private payor coverage

SOZO Systems Sold in U.S.



## Other achievements in FY23

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- **FDA clearance for SOZO Pro**
  - Designed to improve clinical workflow by allowing easier patient transition
  - Expected launch during CY24
- **Extension of clinical trial contract with AstraZeneca**
  - Two clinical trials using SOZO to measure fluid levels in patients with chronic kidney disease
  - Extension providing additional \$1.0 million in revenue bringing total revenue from the clinical trials to \$6.7 million
- **\$30 million capital raise at \$0.13 per share**
  - \$20 million institutional placement announced in May 2023
  - \$10 million oversubscribed Share Purchase Plan announced in June



## Outlook For FY24 and beyond

- **Key focus is to drive Impedimed towards profitable growth:**

- Compelling opportunity with guidelines and expanding private payor coverage
- Increase internal focus on execution that achieves robust sales and commercial outcomes
- Achieve growth with an appropriate cost structure and cost controls

- **Organisation in place to achieve profitable growth:**

- Very capable and motivated core management team
- Distinctive product portfolio with an undeniable commercial opportunity
- New Board completely aligned with interests of investors and shareholders

- **Experienced new leadership focused on driving towards profitable growth:**

- Dr Parmjot Bains as CEO – senior executive roles at Pfizer, ex McKinsey & Co and medical doctor
- McGregor Grant, CFO – 12yrs CFO at Nanosonics driving capital/consumable model

