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Companies Announcements Office Australian Securities Exchange

# ImpediMed 2024 half-year financial results

#### **HIGHLIGHTS**

- Half year revenue of \$4.8 million, compared with \$5.7 million in the previous corresponding period. Reduction largely due to foreshadowed end of AstraZeneca clinical trial program.
- UnitedHealthcare, the largest Private Payor in the United States, updated coverage policy to allow reimbursement claims for relevant CPT code without clinical review.
- 14 states in the US reach critical mass (80% population covered for reimbursement from Private Payors or Medicare). No states had achieved critical mass at 30 June 2023.
- Leadership changes with Dr Parmjot Bains appointed as Managing Director and Interim CEO, and McGregor Grant appointed as Executive Chair and Interim CFO.
- Cash balance at 31 December 2023 of A\$36.9 million.

**ImpediMed Limited** (ASX: IPD) (**ImpediMed** or the **Company**), today announced its Appendix 4D for the half-year ending 31 December 2023.

SOZO sales were disappointing and below the new management's expectations, considering the recent inclusion in the NCCN® Guidelines and increasing payor coverage. Reimbursement remains a fundamental driver for provider uptake beyond early adopters, and critical mass coverage has gained momentum in the most recent quarter. Lead times for SaaS sales are currently around 6 months from lead generation to execution, due to need for customers to synchronise with budget approvals, contracting and IT security assessments. The Company is now prioritizing the high reimbursement states and actively working through the sales process to identify areas where it can streamline in order to shorten the time from lead generation to contract execution and revenue.

Since commencing as CEO in January this year, Dr Bains has been in the field with key account executives and visited numerous customers across 8 states to gain an understanding



of our customer needs and the nature of SOZO® usage. As a result, the Company has prioritised activites to focus on 11 key states, segmented and prioritised the customer lists and aligned on actions to accelerate leads and execute on sales. We remain confident that adoption of this world-class platform technology will accelerate as reimbursement continues to expand across all states in the US, supported by pricing, clinical education and focused execution. We are introducing a SaaS patient-based pricing model within high reimbursement states and accounts. Recent focus of the business has been on breast cancer lymphoedema prevention, supported by the PREVENT Trial protocol. Eighty percent of US sites are measuring leg lymphoedema, which is supported by NCCN® Survivorship Guidelines and reimbursement, and work is being accelerated to capture this larger market opportunity.

The Company has introduced measures to manage cashflow, establishing greater cost discipline in the business and is targeting a 10%-15% reduction in annualised operating costs.

Revenue for the half-year ending 31 December 2023 was \$4.8 million compared with \$5.7 million in H2 FY23, and \$5.7 million in H1 FY23. The reduction was largely due to the foreshadowed end of the clinical trial program conducted by AstraZeneca, which generated revenue of A\$0.1 million in the current half-year period compared with \$0.9 million in H2 FY23, and \$1.2 million in H1 FY23.

During the half-year, the Company sold a total of 57 SOZO units of which 32 units were sold in the US. This compares with 71 units in H2 FY23, of which 46 units sold in the US and 64 units in H1 FY23 of which 32 units were sold in the US.

The Core Business Total Contracted Value<sup>1</sup> (TCV) signed during the half was \$4.0 million compared with TCV of \$7.0 million signed in H2 FY23, and \$6.2 million signed in H1 FY23.

The existing contracts in place as at 31 December 2024 are expected to generate Core Business Annual Recurring Revenue<sup>2</sup> (ARR) of \$10.9 million for the 12 months to 31 December 2024. This compares with ARR as at 30 June 2023 of \$9.3 million and \$8.2 as at 31 December 2022.

#### Reimbursement

As announced in November 2023, UnitedHealthcare, the largest Private Payor in the US, updated its *Commercial and Individual Exchange Medical Policy Omnibus Codes* policy to state that Bioimpedance Spectroscopy (BIS) for Lymphedema Assessment (CPT Code 93702) no longer requires clinical review. The removal of the requirement for clinical review is referred to as "silent coverage", and this policy came into effect in January 2024. Medicare in

<sup>&</sup>lt;sup>1</sup> Total Contracted Value (TCV) includes any consideration for the sale of SOZO Systems as well as the total Software-as-a Service (SaaS) fees for the duration of the signed contracts. Typically, these contracts are for a period of three years with the monthly SaaS fees increasing each year as the contract progresses.

<sup>&</sup>lt;sup>2</sup> Annual Recurring Revenue (ARR) represents the amount of revenue reasonably expected to be recognised for the next 12-month period based on existing contracts, assuming installation upon sale and no churn. As the Company is now recognising revenue in equal monthly amounts across the term of each contract, rather than adjusting for any increased pricing during the contract, it will no longer separately provide an ARR number for the subsequent year (i.e. from months 13-24) as it is expected this will be similar, with the only change arising from contracts that expire and are not renewed during the subsequent year.



the US, along with 39 other Private Payors, currently provide silent coverage for CPT Code 93702. In addition, there are 14 Private Payors that have published positive medical policies.

Taking into consideration recent changes regarding the way policy decisions are implemented for members of the Blue Cross Blue Shield Association (which were described in ImpediMed's Q1 FY24 Activities Report), the Company estimates approximately 85% of Private Payors will be providing coverage of CPT Code 93702 by the end of FY24.

Since inclusion of BIS for Lymphedema Assessment in the NCCN Guidelines<sup>®</sup> in March 2023, with the updated policy from UnitedHealthcare along with other Private Payor policy changes that have come into effect, there are now 14 states that have achieved 'critical mass'. The Company defines critical mass as having greater than 80% of the population covered for reimbursement by either Medicare or Private Payors. Two states achieved critical mass by the end of Q1 FY24 with an additional 12 states achieving critical mass since then, bringing the total to 14 states.

The Company has identified 11 states that it considers high priority from a commercialisation perspective based on potential patient population, medical leadership in lymphoedema prevention and payor coverage. Of these, 7 states have achieved critical mass. The Company believes all 11 high priority states are likely to achieve critical mass by April 2024 and these will be a key focus for the Company's near-term sales and marketing efforts, noting the historical 6 month sales lead time.

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#### Financial results

		FY24	FY23	FY23	Change	vs PH	Change	vs PY
\$A millions		1H	2H	1H	\$	%	\$	%
Revenue		4.8	5.7	5.7	(0.9)	-16%	(0.9)	-15%
Gross profit		4.2	5.0	4.8	(8.0)	-16%	(0.7)	-14%
%		86.8%	87.1%	85.7%				
Ope	erating expenses							
	alaries and benefits	(11.0)	(9.2)	(11.0)	(1.7)		0.0	
Sh	nare-based payments	0.2	(0.8)	0.1	1.0		0.1	
	onsultants and professional fees	(1.8)	(1.1)	(1.6)	(0.7)		(0.3)	
	dministrative and governance	(1.5)	(1.4)	(1.3)	(0.2)		(0.2)	
	epreciation and amortization	(1.2)	(1.3)	(1.2)	0.1		(0.0)	
Tr	avel expenses	(8.0)	(0.6)	(0.5)	(0.2)		(0.3)	
R	esearch and development	(0.1)	(0.1)	(0.5)	(0.0)		0.4	
Ot	ther expense	(8.0)	(1.1)	(1.1)	0.2		0.3	
Opera	ating expenses	(17.1)	(15.6)	(17.1)	(1.5)	-9%	(0.0)	0%
Other income		2.4	0.5	1.1	1.9		1.3	
loss from operations		(10.5)	(10.1)	(11.1)	(0.4)	-4%	0.6	5%
Finance income, net		0.8	0.4	0.3	0.4		0.5	
Net loss before tax		(9.7)	(9.7)	(10.8)	(0.0)	0%	1.1	10%
Income tax		(0.0)	(0.0)	(0.0)	(0.0)		0.0	
Net loss after tax						00/	1.1	400/
Net loss after tax		(9.7)	(9.7)	(10.8)	(0.0)	0%	1.1	10%
Cash	and cash equivalents	36.9	45.7	26.2	(8.8)		10.7	
					(333)			
	Revenue for the half-year ending 31 December 2023 was \$4.8 million compared with \$5.7							
	million in the previous corresponding period with most of this reduction being due to lower							
	revenue from clinical trial services during the period. As foreshadowed, the clinical trial							
	program conducted by AstraZeneca, generated revenue of A\$0.1 million in the current half-							
	year period compared with \$0.8 million in H2 FY23, and \$1.2 million in H1 FY23.							
	In provious periods, ImpediMed separately reported revenue associated with the initial sale of							
	In previous periods, ImpediMed separately reported revenue associated with the initial sale of SOZO Systems as Device Revenue and the remaining revenue associated with each contract							
	·							
	was reported as Recurring Subscription Revenue. Furthermore, the amount of Recurring							_
	Subscription Revenue reported in each period reflected the increased pricing built into each							

As the device is an integral part of the ongoing service provided, and based on high contract renewal rates and a continued low churn rate, for this period and going forward, the Company will report all revenue associated with each contract as Revenue from Contracts with Customers, recognised in equal monthly amounts over the term of each contract. This change had no material impact on the current period results. Management considers this approach



reflects the contracts being established with customers following the inclusion of bioimpedence spectroscopy in the National Comprehensive Cancer Network Guidelines (NCCN Guidelines®), and the expansion of reimbursement coverage by Private Payors.

Operating expenses for the half-year were \$17.1 million compared with \$15.6 million in H2 FY23 and \$17.1 million in H1 FY23. The increase in operating expenses compared with H2 FY23 was driven by costs associated with General Meeting held in September 2023 and the departure of the former CEO and CFO.

During the half-year the Company had net operating cash outflows \$6.8 million compared with \$5.9 million in H2 FY23 and \$12.2 million in H1 FY23. The increase in operating cash outflows compared with H2 FY23 was primarily driven by increased costs associated with staff, including recruitment fees and short term incentives that are paid in the first half. These increases were offset by cash receipts associated with the Federal Government's R&D credit and the US Government's employee retention credit.

During the current half, H2 FY24, ImpediMed commenced introducing measures to more tightly manage cashflow and establish greater cost discipline in the business with the aim of reducing annualised operating costs by 10%-15% by the end of FY24.

Cash and cash equivalents at 31 December 2023 were \$36.9 million, compared with \$45.7 million at 30 June 2023 and \$26.2 million at 31 December 2022.

As previously announced, in November 2023 McGregor Grant was appointed CFO, initially on an interim basis and Dr Parmjot Bains was appointed as CEO and Managing Director, also initially on an interim basis, commencing in that role on 8 January 2024. Dr Bains and Mr Grant are currently in discussions with the Board regarding their appointment on a permanent basis.

Approved for release by the Board of ImpediMed Limited

### Investor conference call

Investors are invited to join a conference call hosted by Interim CEO and Managing Director Dr Parmjot Bains and Interim CFO and Executive Director McGregor Grant on Tuesday 27 February 2024 at 11:00am AEDT (Sydney/Melbourne) /10:00 am AEST (Brisbane).

To pre-register, please follow this link: <a href="https://s1.c-conf.com/diamondpass/10037236-m1xo3s.html">https://s1.c-conf.com/diamondpass/10037236-m1xo3s.html</a>.

For more information, contact Dr Parmjot Bains MD/Interim CEO or McGregor Grant Interim CFO on +61 7 3860 3700



# 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.

# **Forward Looking Statements**

This announcement contains or may contain forward-looking statements that are based on ImpediMed Limited (ImpediMed) 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. Any forward-looking statements, including projections, guidance on future revenues, earnings and estimates, are provided as a general guide only and should not be relied upon as an indication or guarantee of future performance.

While management has prepared this information based on its current knowledge and understanding and in good faith, there are risks and uncertainties involved which could cause actual results to differ from projections. You should not place undue reliance on forward-looking statements which speak only as of the date when made. Except as required by law, 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 and no representation, warranty or assurance (express or implied) is given or made in relation to any forward-looking statement by any person (including ImpediMed Limited).