

9 November 2022

#### **ASX ANNOUNCEMENT**

#### AstraZeneca Further Extends Clinical Trial Contract

# **Key Highlights**

- AstraZeneca extends its contract for a Phase IIb trial, which utilises 210 SOZO<sup>®</sup> devices to measure fluid volume in patients with chronic kidney disease, for an additional 8 months.
- The extension of the trial will generate over \$1.0 million of additional revenue, which will be recognised over the remainder of the 2023 financial year.
- In total, over \$6.7 million in contract value has been signed under the various AstraZeneca trial agreements.

ImpediMed Limited (ASX.IPD), today announced the details of the third contract extension related to the use of the SOZO Digital Health Platform in a clinical trial being conducted for AstraZeneca. The Phase IIb trial is using the SOZO to track patient fluid volume in a pharmaceutical study focused on chronic kidney disease. The trial has been extended from 21 months to 29 months, with 210 SOZO devices being utilised in the extension.

In total, the contracts will generate over \$6.7 million in revenue across the trials. The Company recognised approximately \$5.7 million in revenue to date (through 30 September 2022) under these contracts. The remaining \$1.0 million of the revenue will be recognised throughout the remainder of the 2023 financial year.

The Company previously announced AstraZeneca is using SOZO to track patient fluid volume in two separate clinical trials. A combined 434 SOZO devices have been leased across over 28 countries over the course of both trials. The first trial was focused on heart failure and chronic kidney disease and the second only on chronic kidney disease. The use of SOZO in that trial is now complete.

The current AstraZeneca trial that has been extended is using SOZO to monitor body fluid volumes as they evaluate the efficacy, safety and tolerability of a combination of two AstraZeneca drugs in heart failure patients with chronic kidney disease. This Phase IIb trial began in November 2020 and the use of SOZO within the trial is now scheduled to be completed in April 2023. The trial is being run by a contract research organisation on behalf of AstraZeneca.

Under the terms of the agreement, and in alignment with the Company's SaaS business model, each device will have a monthly license fee for the duration of the trial. ImpediMed will retain ownership of the devices at the conclusion of the trials.

Approved for release by the Interim CEO and Director, Mr David Anderson.

#### **Contact Details**

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# About ImpediMed

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

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

For more information, visit www.impedimed.com.

## **About SOZO Digital Health Platform**

SOZO, the world's most advanced, non-invasive bioimpedance spectroscopy (BIS) device, delivers a precise snapshot of fluid status and tissue composition in less than 30 seconds. Using ImpediMed's BIS technology. SOZO measures 256 unique data points over a wide spectrum of frequencies from 3 kHz to 1000 kHz. 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 or renal failure, and can be used to monitor and maintain overall health – all on a single device.

For more information, visit: https://www.impedimed.com/products/sozo/.

## **About SOZO Fluid Analysis for Heart Failure**

All The factor of the factor o The SOZO fluid analysis for heart failure provides an objective measure of fluid overload in heart failure patients. It utilises ImpediMed's HF-Dex™ heart failure index which is a measure of extracellular fluid as a percent of total body water. HF-Dex is presented on BIS-derived reference ranges which indicate normal fluid volumes, elevated fluid volumes, and fluid overload, which is defined as HF-Dex greater than 51%. When used as part of a clinical assessment of heart failure, SOZO helps differentiate between fluid and tissue-related weight changes to track response to medication changes and to provide a marker for readmission when HF-Dex is higher than 51%.

For more information, visit: https://www.impedimed.com/healthcare/heart-failure/.

# **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.