



4 November 2021

ASX ANNOUNCEMENT

AstraZeneca extends and increases HF & Renal Contract

Key Highlights

- **AstraZeneca extends its contract for the Phase IIb trial, which is utilising SOZO® to measure fluid volume in patients with heart failure and chronic kidney disease, by 3 months.**
- **In addition to extending the contract, AstraZeneca has increased the number of SOZO devices required by 36, taking the total number in this trial to over 210.**
- **With the additional 36 devices, over 410 SOZO devices in total will be leased across 28 countries for the two ongoing AstraZeneca trials.**
- **The extension and expansion of the trial will generate an estimated value of over \$500k in additional revenue to be recognised in coming quarters.**

ImpediMed Limited (ASX:IPD), today announced a contract extension and increase of its SOZO Digital Health Platform to be used in one of the clinical trials being conducted for AstraZeneca. The Phase IIb trial is using the SOZO devices to track patient fluid volume in a pharmaceutical study focused on heart failure and 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 Company previously announced preliminary expectations for the contract as a requirement of the October 2021 Capital Raise process and has now finalised the agreement. In total, the contracts are expected to generate over \$5.0 million in revenue across the trials. The Company recognised \$1.8 million in revenue under these contracts in FY'21. The remainder of the revenue will be recognised throughout FY'22 and FY'23.

The Company previously announced AstraZeneca is using SOZO to track patient fluid volume in two separate clinical trials. The first is focused on heart failure and chronic kidney disease and the second only on chronic kidney disease. A combined 375 SOZO devices were to be leased across over 25 countries for both trials. In total, 411 devices will now be used across both trials, generating in excess of \$5.0 million in revenue.

The AstraZeneca study 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 is now scheduled to be completed in July 2022. 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 study. ImpediMed will retain ownership of the devices at the conclusion of the trials.

"To date, the feedback on SOZO has been very positive. The trial is providing a significant number of cardiologists and nephrologists, both in the US and globally, firsthand experience with SOZO," commented Richard Carreon, Managing Director and CEO of ImpediMed.

"Heart failure and chronic kidney disease are two of our three strategic focus areas, and this contract addition provides continued validation of the applicability of our technology in both patient populations.

The endorsement is timely, as the Company begins the launch of SOZO into the cardiology market and progresses towards an FDA clearance in Renal through the Breakthrough Device Designation Program,” he added.

Approved for release by the Managing Director and CEO, Mr Richard Carreon.

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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

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.