



23 December 2022

ASX ANNOUNCEMENT

Update to Expected Release of NCCN Guidelines®

ImpediMed Limited (ASX:IPD), today announced an update on the expected release of the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). The Company had previously stated an expectation that the NCCN Guidelines would likely be updated this calendar year. While this expectation has not been met, it is important to note that the updates to both the NCCN Guidelines for Breast Cancer and NCCN Guidelines for Survivorship, post their respective NCCN annual panel meetings, are still pending.

Background

In February 2022, post the release of the successful PREVENT Trial publication, a submission was made to the NCCN Breast Cancer Panel, seeking an amendment to the NCCN Guidelines for Breast Cancer. A subsequent submission was made to the NCCN Survivorship Panel later in the year. The expectation was that harmonised guideline updates would be released before the end of the calendar year, based on the NCCN Breast Cancer Panel submission review in late August 2022 and the NCCN Survivorship Panel submission review at the Annual Meeting in October.

Basis of previous expectation

The expectation of a release within the 2022 calendar year was based on the historical frequency of meetings. In the 2021 calendar year, the NCCN Breast Cancer Panel conducted six out of cycle meetings in addition to the two-day annual meeting. Three of these meetings occurred after the 2021 August Annual Meeting with the final meeting being conducted on December 17, 2021. Guideline changes were subsequently released on December 20, 2021. With this cadence of meetings, ImpediMed was comfortable with the expectation that the result from the February submission would be released before calendar year end. The Company also took into consideration the previous three years the lowest number of out of cycle meetings was four. The Company had not anticipated a significant reduction of the out of cycle meeting frequency of six meetings to one.

Update

ImpediMed wishes to thank investors for their continued patience. Unfortunately, there is no timeline guidance provided by the NCCN, so our expectations can only be derived from observing historic precedence. With the NCCN Breast Cancer Panel submission being made in February 2022 and the annual meeting occurring in August 2022, we continue to believe that updates should be forthcoming in the near future.

As we have consistently stated, reimbursement is the highest priority for the Company and the NCCN Guidelines are an important part of the dual-path strategy, as they would be an accelerator to widespread reimbursement. In addition, the Company continues to focus on the traditional pathway to reimbursement and will update the market on the progress of the reimbursement program, including any new information on the potential timing of the NCCN Guidelines, with the 4C quarterly results to be released in late January 2023.

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

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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/>.

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.