

# **Osprey Medical Financial Results for FY2019**

**February 25, 2020- Minnesota, United States and Melbourne, Australia** – Osprey Medical (ASX: OSP) today released its Appendix 4E Preliminary Final Report for the full year ended 31 December 2019 and its audited consolidated financial statements, with accompanying notes.

#### **Key financial details**

- Full year worldwide net revenues up 46% over prior year
- Full year net cash used in operating activities up 1% over prior year
- Cash and cash equivalents of US\$8.3m /A\$12.2m at 31 December 2019

### **Operational achievements**

- 53% year-on-year growth in unit sales and 46% growth in revenue
- Group Purchasing Contract Awards (GPO) covering 50% of US hospitals
- DyeVert™ featured in nine podium presentations at six major cardiology meetings in 2019

#### Strong sales momentum in the United States

Osprey delivered strong DyeVert unit sales growth in 2019 with 11,038 units up 53% over 2018 (7,201 units). Unit sales growth in the full portfolio (DyeVert, DyeTect and Syringes) was up 53% in 2019 at 11,838 as compared to 2018 total unit sales of 7,723. The customer base of hospitals who have purchased DyeVert increased by 23 hospitals in 2019 to a total for the year of 159 hospitals compared to 136 in 2018.

Full year worldwide revenues of US\$3.7m\_were up 46% over 2018 revenues of US\$2.5m. A focus of the Company in 2019 was to increase revenues while controlled costs and pleasingly net cash used in operating activities was up only 1% in 2019 over 2018 (US\$16.9m in 2019 vs US\$16.8m in 2018). Cash and cash equivalents of US\$8.3m /A\$12.2m at 31 December 2019 (2018: US\$25.3m).

Osprey's sales strategy is focused on leveraging U.S. Food and Drug Administration (FDA) claims received for dye reduction, along with medical society guidelines that call for reduced dye use in Chronic Kidney Disease (CKD) patients to avoid Contrast Induced Acute Kidney Injury (CI-AKI). Osprey has successfully established selling systems and tools to drive product adoption across all territories using these medical society guidelines, as well as a market development approach highlighting the advantages of DyeVert Plus relative to other devices.

## **GPO-focused sales strategy**

In 2019, Osprey had contracts with 5 US multi-hospital systems (referred to as GPOs) which cover 50% of heart hospitals in the U.S. Premier is the largest GPO contract for Osprey with over 4000 U.S. hospitals covered under this agreement and 2000 that do Cardiology procedures. In March 2019 Premier published an abstract to the American College of Cardiology annual scientific sessions titled "Acute Kidney Injury Incidence, Risk Factors, and Costs among U.S. Patients Undergoing Percutaneous Coronary Procedures". This study examined charge code data from 749-member hospitals with over 2.8 million CKD patients undergoing angiography procedures (heart imaging and/or stenting) for the period 2012-2017. Key findings provide compelling evidence of the growing occurrences, health consequences and the economic burden of AKI, as follows:

- AKI in CKD patient population undergoing angiography increased from 18% to 28% from 2012 to 2017
- Mortality rates post angiography were 61% higher in CKD patients who had AKI events

• Economic burden to all healthcare providers for AKI 90 days post angiography was US\$1.67 billion over the five-year period of the study.

The company used the study throughout 2019 to target Premier hospitals and drive adoption of the DyeVert system. Additional data analysis continues within Premier to record AKI reduction with a kidney care protocol featuring the DyeVert system.

#### Podium presentations and publications

A key component of Osprey's commercialisation strategy is to make podium presentations at leading industry events to drive product awareness among the physician community. Osprey's technology was featured in nine podium presentations at key cardiology conferences in CY2019. These included:

- Abstract publication at the National Cardiovascular Data Registry annual meeting (March 2019)
- A presentation and two abstracts at the American College of Cardiology conference (March 2019)
- A presentation and two abstracts at the Society of Cardiovascular Angiography and Interventions conference (May 2019)
- Two presentations at the Transcatheter Cardiovascular Therapeutics conference (October 2019)

These presentations prominently featured the DyeVert and DyeVert Plus System benefits of >40% dye savings and dye monitoring, without compromised image quality, which align with medical society guidelines to minimize and monitor dye in patients with poor kidney function. In three of the publications the hospitals showed AKI reductions of 46%-63% following a protocol including the DyeVert System.

#### Outlook

Osprey remains focused on establishing the DyeVert System as the standard of care for all physicians treating patients at risk of CI-AKI. In 2020 the Company expects sales revenue to continue to grow as the number of hospitals and physicians using DyeVert and DyeVert Plus increases, with increased sales momentum from Osprey's GPO contracted hospital focus and the adoption of the new DyeVert Ez. The Company will continue to expand its strong and growing network of key opinion leading physicians and hospital centres of excellence, which is expected to provide the framework for sales growth over the course of CY 2020 and beyond.

The Company expects revenue growth in Europe in 2020 as it is in advanced discussions with a party interested in European distribution rights. The Company expects these discussions will lead to a definitive distribution agreement in the second quarter of 2020 and for sales under this agreement to commence in the second half of 2020.

The Appendix 4E and attached audited consolidated financial statements for years ended 31 December 2019 and 2018 have been prepared in U.S. dollars. Also attached is the Report of the Independent Auditor, Baker Tilly Virchow Krause, LLP.

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Osprey Medical's vision is to make heart imaging procedures safer for patients with poor kidney function. The amount of dye (contrast) used during angiographic imaging procedures increases the patient's risk for dye-related kidney damage known as Contrast Induced Acute Kidney Injury (AKI). The Company's core technologies originated from research conducted by Dr David Kaye at Melbourne's Baker Institute. Its proprietary dye reduction and monitoring technologies are designed to help physicians minimize dye usage and monitor the dose of dye real time throughout the procedure. The Company's DyeVert™ Plus System reduces contrast while maintaining image quality in a self-adjusting easy-to-use design that monitors dye usage. Osprey Medical's Board and Management are comprised of experienced and successful personnel with established track records covering medical device development, regulatory approvals, sales and marketing, and mergers-acquisitions. Osprey Medical's advisory board comprises world-recognised experts in heart and kidney diseases.

## **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 commercialize our products including our estimates of potential revenues, costs, profitability and financial performance; our ability to develop and commercialize 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. Osprey 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. Osprey may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements.

## **Foreign Ownership Restriction**

Osprey's CHESS Depositary Interests (CDIs) are issued in reliance on the exemption from registration contained in Regulation S of the US Securities Act of 1933 (Securities Act) for offers or sales which are made outside the US. Accordingly, the CDIs have not been, and will not be, registered under the Securities Act or the laws of any state or other jurisdiction in the US. The holders of Osprey's CDIs are unable to sell the CDIs into the US or to a US person unless the re-sale of the CDIs is registered under the Securities Act or an exemption is available. Hedging transactions with regard to the CDIs may only be conducted in accordance with the Securities Act.