

# **Osprey Medical Financial Results for FY2020**

**February 26, 2021- 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 2020 and its audited consolidated financial statements, with accompanying notes.

### **Key financial details:**

- COVID-driven cost reductions leading to operating expenses of US\$13.8m, a 31% reduction compared to
  prior corresponding period (pcp). In addition, a 25% reduction in net cash used in operating activities, down
  from US\$16.9m in pcp to US\$12.7m in FY20
- Total sales revenue of US\$1.7m, down from US\$3.7m in pcp due to impact of COVID-19 and limited hospital access
- US\$5.8m at 31 December 2020, with additional funding subsequent to the year including ~US\$10.0m<sup>1</sup> from options exercised and ~US\$1.1m loan from the US Paycheck Protection Program

# **Operational achievements:**

- Worldwide sales expansion with global giant, GE Healthcare, selling Osprey's portfolio across Europe and parts of Asia. In addition, Osprey has entered the ANZ market for the first time through Regional Health Care Group
- Cost-effective expansion across US with Independent Sales Agency (ISA) agreement with BioCore covering 8
  new states, with more to be finalised in the near-term in addition to our direct coverage over existing states
- CE Mark for DyeVert Power XT 2<sup>nd</sup> Generation and awaiting outcome of FDA application. This device covers the remaining ~40% of the coronary angiography market, providing Osprey full coverage with its DyeVert portfolio

Worldwide sales expansion: Over the last 12 months, Osprey has expanded its commercial reach worldwide for sales of the DyeVert technology. In July 2020, Osprey signed a four-year strategic alliance with GE Healthcare for exclusive distribution rights to Osprey's product portfolio in Europe, Russia, Middle East, Africa, Central Asia and Turkey. GE Healthcare's Pharmaceutical Diagnostics unit develops and supplies imaging agents used to support approximately 90 million procedures per year globally, equivalent to three patients every second. Its range of products include iodinated X-ray contrast media used in interventional and other diagnostic procedures including coronary angiography making them a well-suited partner for commercialization of the DyeVert System. The four (4) year exclusive distribution agreement enables GE Healthcare to commercialize Osprey's products within the Region. During the term of this agreement transfer pricing has been fixed over the 4-year period and GE has escalating minimum purchase volumes yearly.

Following the GE Healthcare announcement, Osprey partnered with Australian-owned medical distribution company Regional Health Care Group Pty Ltd (RHCG) which will see RHCG exclusively distribute Osprey's products across Australia and New Zealand.

Osprey expanded its US sales coverage in 2020 with the addition of a strategic Independent Sales Agency (ISA) agreement with BioCore Inc., an independent sales group that specialises in selling Cardiac Surgery, Electrophysiology and Cath Lab products. The addition of BioCore, and planned future ISA additions, forms a part of Osprey's broader vision to increase its geographic coverage whilst at the same time focus on maintaining a lean business model. The ISA strategy provides Osprey with a dual-pronged sales approach across the US, via both ISAs and direct sales reps and the agreement has been structured to leverage the key advantages of both the ISA and

direct sales force. Practically, Osprey's direct sales reps will continue to focus on the regions in which they operate, however they will also work closely with the ISAs to help convert potential customers in new regions. Osprey is in active discussions with several ISAs at this stage and hopes to continue to expand its geographic coverage in the near-term.

Key Payor progress, podium presentations and publications: In early 2020, Osprey announced that the National Institute of Health and Care Excellence (NICE) in the UK issued a MedTech Innovation Briefing (MIB) on DyeVert for reducing contrast media in coronary and peripheral angiography. Alongside this, a peer-reviewed publication to accompany the MIB on the cost-utility of DyeVert was published in The Pharmacoeconomics & Health Economics Journal. In October the DyeVert was selected by NICE for Guidance consideration which could lead to a recommendation by NICE for the use of DyeVert to reduce Contrast-Induced Acute Kidney Injury (CI-AKI) in 2021.

DyeVert was also featured at the SCAI 2020 Scientific Session with two abstracts on *Procedure-Based Strategies to reduce Contrast-Induced Acute Kidney Injury*. Both studies reported on the use of Osprey's DyeVert System to reduce AKI in patients undergoing coronary angiography.

An important peer reviewed manuscript was published in April on CI-AKI reduction in acute coronary syndrome (heart attack) patients was published by Professor Briguori earlier this year. In this controlled retrospective two arm study the DyeVert system was shown to reduce CI-AKI in heart attack patient by 58%.

In July 2020, we were very pleased to receive a Supplier Horizon Award from Premier Inc. We were one of just nine suppliers to win the prestigious award, and we were the only cardiovascular supplier to receive the award this year. The award recognizes suppliers who have made a positive impact to patient care and who lower healthcare costs.

**Portfolio Expansion:** Early in 2020 we received CE Marking for our DyeVert Power XT 2nd generation device with the added benefits of displaying the contrast saved throughout the procedure allowing real time contrast monitoring. The DyeVert Power XT device is expected to be the core product in the DyeVert portfolio that is being commercialised by GE Healthcare. The DyeVert Power XT is for physicians who prefer a powered injection machine to preform coronary angiograms. Approximately 40% of the US and European market uses power injection machines and 60% uses manual injection syringes; thus Osprey now has full coverage of the market in Europe. The DyeVert Power XT was also submitted to the FDA and clearance is expected in 2021.

**Performance:** 2020 was a year defined by COVID-19 which resulted in the postponement of elective heart procedures, restricted sales rep access to hospitals and the suspension of new technology evaluations for the majority of the year. In addition, sales across Europe were stagnant due to COVID-19 related hospital procedure suspensions and GE's commercial launch being slowed by the pandemic. Pleasingly, Osprey received its first warehouse order from GE Healthcare in the fourth quarter despite an upswing in COVID-19 restrictions, with hospitals ordering in Italy, Spain and UK.

As a result of COVID-19 disruptions, Osprey revenues declined to US\$1.7m in 2020 as compared to US\$3.7m in 2019. In response, Osprey initiated an aggressive cost reduction program which resulted in a 31% decline in total operating expenses in 2020 as compared to 2019 (US\$13.8m versus pcp of US\$20.1m). The cost-saving measures instated in 2020 serve as the foundation for our long-term strategy of increasing our worldwide sales coverage with cost effective Independent Sales Agents in the US and GE distribution of the Osprey portfolio outside of the US.

The Company successfully raised gross proceeds of A\$14.7m in 2020 with A\$12.8m from the Entitlement Offer and Shortfall Placement, A\$1.9m in loan proceeds from the US Paycheck Protection Program and A\$1.7m from the exercise of unlisted options issued under the Entitlement Offer. The Company had cash and cash equivalents of US\$5,787,030 at 31 December 2020 compared to US\$8,276,720 at 31 December 2019. As announced to the market on 23 February 2021, additional funding of A\$12.8m/US\$10.0m¹ has been received following the exercise of unlisted options issued under the 2020 Entitlement Offer and the Company has received a second loan of US\$1.1m from the US Paycheck Protection Program.

**Outlook:** Contrast-Induced Acute Kidney Injury is a rapidly growing problem which results in poor patient outcomes and increased hospital costs. As the pandemic subsides and hospitals explore ways to improve coronary angiography patient outcomes and reduce costs, DyeVert provides the solution as it has been proven to reduce CI-AKI. Overall, Osprey faces a potential market opportunity of ~\$1.1B and is committed to expanding its reach globally to protect patients from CI-AKI.

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 expanded its sales footprint with cost efficient ISAs and GE distribution outside of the US which provides the framework for sales growth over the course of CY2021 and beyond.

 $^{1}$  AUD / USD = 0.78

This release has been authorised for lodgement to ASX by Mike McCormick, CEO of Osprey Medical.

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#### About Osprey Medical (ASX: OSP)

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 (CI-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<sup>TM</sup> 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.