

# 2019 Annual Meeting of Stockholders - Chairman's Address and Presentation by President and CEO

**9 May 2019 - Minnesota, United States and Melbourne, Australia –** Osprey Medical (ASX:OSP) is pleased to present the attached copy of the Chairman's address and the presentation by the President and CEO which are to be delivered at the 2019 Annual Meeting of Stockholders at Johnson Winter & Slattery's Melbourne office, Level 34, 55 Collins Street, Melbourne, Victoria, Australia on Thursday, 9 May 2019 at 9.00am Australian Eastern Standard Time (Wednesday, 8 May 2019 at 6.00pm U.S. Central Daylight Time).

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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™ 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.



# OSPREY MEDICAL INC – 2019 ANNUAL MEETING OF STOCKHOLDERS CHAIRMAN – MR JOHN ERB

Good morning ladies and gentlemen,

My name is John Erb and as Chairman of Osprey Medical I am pleased to welcome you to the 2019 Annual Meeting of stockholders.

It is now 9.00am, and I note that this is a properly constituted meeting and that a quorum is present. I therefore declare this Annual Meeting of Stockholders of Osprey Medical open and welcome each of you.

I would like to first introduce our President and Chief Executive Officer, Mike McCormick. With Mike today are our directors - Andy Jane, Sandra Lesenfants, Neville Mitchell and Chris Nave. Our Directors bring a diverse range of expertise and highly complementary skillsets to guide the overall progress of the Osprey Medical business.

Since our meeting last year, I am pleased to report Osprey Medical has delivered on several key milestones, particularly around product development, education and awareness, and achieving commercial growth. Some highlights in the past year include Osprey's increased focus on driving sales with Group Purchasing Organisations (or GPOs) and the subsequent signing of a purchasing agreement for Premier, one of the largest GPOs in the US. In the third quarter of 2018 Osprey received FDA clearance and then commercially launched its next-generation DyeVert Plus EZ system. The device has been very well received by our clinician users and new adopters of our technology, which Mike will cover in his presentation. Other highlights include launching a pilot commercialisation program in Europe, ramping up our sales force, and our continued investment in healthcare education and awareness for Chronic Kidney Disease and Acute Kidney Injury among US medical practitioners.

You will have read in our 2018 Annual Report that was released in March of this year that our sales momentum in US cath labs has continued to see growth, with a 56 percent increase in year-on-year revenue at the year's end. In addition to this, the Company has seen a 40 percent year-on-year growth in the number of hospitals purchasing DyeVert products, which at the end of 2018 stood at 137. This has largely been the result of strong performance of Osprey's sales and marketing efforts and the high rate of converting sampling hospitals in our pipeline to purchasing hospitals. Our strong sales performance was supported by a 39 percent increase to our total sales infrastructure last year, with a particular focus on recruiting GPO specialists to execute next stage of the Company's sales

strategy. Shareholders should note that the growth rate of our revenues materially outpaced the growth rate of our operating expenditure during the year. We believe that as our education and awareness build out continues to gain momentum, and our user experience expands these benefits will be maintained throughout 2019. With higher volumes, our gross product margins will continue to expand as a significant portion of our cost of goods relates to manufacturing overheads such as labour. Importantly, our facilities in Minneapolis have sufficient manufacturing capacity to meet expected demand in future periods.

A particular core focus of Osprey Medical this past year has been on driving sales through relationships with Group Purchasing Organisations. In the US Group Purchasing Organisations are made up of member hospitals designed to leverage their collective experience to improve patient outcomes and lower healthcare costs. As Mike will discuss in greater detail, this strategy has seen Osprey execute four GPO-based contracts representing hospitals that collectively account for 50% of acute kidney injury cases in the United States each year.

Our most significant GPO contract is with Premier, Inc, one of the largest GPOs in the US with over 4,000 member hospitals. In December 2018 Osprey Medical was the only company awarded the Technology Breakthroughs award by Premier in the heart products category, a testament to the stand-out nature of DyeVert and its ability to improve outcomes for patients with chronic kidney disease, lower hospitals' cost of care, and save clinicians valuable cath lab resources. Our agreement with Premier allows its 4,000 member hospitals easier access to the DyeVert system at pre-negotiated pricing, and we expect to see further unit sales growth from Premier hospitals in coming quarters.

In terms of our sales mix, we have seen an increasing contribution of DyeVert sales originate from hospitals under a GPO contract. We have a pipeline of GPOs under active negotiation and expect to sign additional contracts during 2019.

Customer feedback from our purchasing hospitals over the past year continues to be very positive. Our customers have praised the seamless integration of the DyeVert into the cath lab, as well as the easy set-up, priming and air removal. Customers have also praised the integral role DyeVert has played in lowering the cost of care, and supporting the cardiology departments' risk management protocol for patients with CKD. Customer feedback continues to play a vital role in Osprey's product development and marketing processes, and we continue to invest in developing our technology to effectively meet customers' needs.

In September last year, Osprey initiated pilot commercial activities in Europe, signing an agreement with Device Access UK to begin a market access process with the UK National Health Service, or NHS. The process is expected to take twelve months and if successful will ultimately lead to a guidance recommendation from the UK's National Institute for Health and Care Excellence for adoption by NHS hospitals. This is a tremendous opportunity to commercialise the DyeVert system in Europe, and establish its routine use as a new standard of care for NHS patients with chronic kidney disease.

As a business, we continue to invest in the incremental and ongoing innovation, as we develop our technology to better suit transforming healthcare needs. In November last year, Osprey Medical

launched its next-generation DyeVert EZ system, following FDA clearance DyeVert EZ offers customers a simplified set-up and easy-to-remember priming process, with fewer system components that require air removal. At the end of the first quarter of 2019 DyeVert EZ made up approximately 60% of total DyeVert unit sales, and continues to show strong acceptance by the clinical community.

In mid-April this year, Osprey Medical reported its quarterly results for the period ended 31 March. The period was Osprey's 18th consecutive quarter of unit sales growth, with total DyeVert unit sales up 73% year-on-year at 2,634 units. Our cash receipts were also up 70% at US \$854 thousand dollars. The total number of purchasing hospitals grew in Q1, with 140 hospitals purchasing DyeVert, and a healthy pipeline of 20 hospitals in the sample-to-purchase phase. I will now take a moment to comment on the Company's current cash position. As of the end of March this year, the Company had a healthy cash reserve of US\$20.1 million. This follows a successful \$14.3 million Australian dollar capital raising to accelerate Osprey's GPO focused sales strategy, corner stoned by the large Australian institutional investor Allan Gray. We welcome them, and our new shareholders to the Company. As you have heard me say, and as will be reinforced by Mike in his presentation, the investment into our GPO strategy is now underway, with our main focus on penetrating deeper within existing contracted GPO accounts and opening new accounts in hospitals covered by one or more of our GPO contracts. We additionally expect to grow Osprey's field sales representation over the course of the year.

Looking to the year ahead, we are very pleased with the operational and sales progress Osprey has made this past year. We expect to see this momentum continue across our GPO sales, education and awareness raising efforts, and the ongoing development of our dye-saving technologies.

Before I conclude I would like to thank my fellow board members, our President and CEO Mike McCormick and the entire staff and management at Osprey Medical, for your continued dedication in ensuring the company's success.

I will now call upon Mike to outline our strategic priorities and further update on you on Osprey's progress over the past twelve months.



**Annual General Meeting CEO Presentation** 

**ASX:OSP** 

9 May 2019

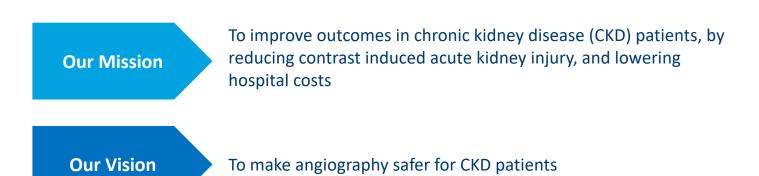




## Company snapshot



- Osprey Medical is focused on transforming the standard of care for chronic kidney disease (CKD) patients
- Valuable and innovative product portfolio with FDA-cleared, TGA-cleared and CE-Marked products
- DyeVert<sup>™</sup> is the only device with an FDA cleared claim for contrast dye reduction without compromised image quality for patients undergoing angiography procedures
- Approx. 30% of all angiography patients are at risk of contrast induced acute kidney injury (CI-AKI), a frequent and dangerous complication for patients and expensive for hospitals to manage
- US\$1.65 billion total addressable market minimal penetration to date



## Company overview



### **Public Market Overview**

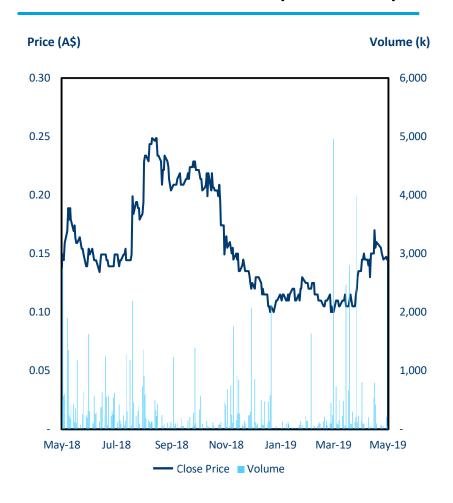
Share price (1-May-19)	A\$0.15
52 week low / high	A\$0.085 / A\$0.255
Number of shares (m)	431.8
Maybet soultalisation	
Market capitalisation	A\$62.6m
Cash (31-Mar-19) <sup>1</sup>	<b>A\$62.6m</b> US\$20.1m / A\$28.7m
·	·

Note: Assumes AUD:USD exchange rate of 0.70

### **Shareholder Overview**

Shareholder	CDIs	%
Brandon Capital Partners	116.3m	26.9%
Allan Gray	73.7m	17.1%
CM Capital	34.0m	7.9%
Kinetic	23.8m	5.9%

## **Share Price Performance (12 months)**



Source: IRESS; market data as at May 2019

Notes. (1) Assumes AUD:USD exchange rate of A\$:US\$0.70

# Operating highlights FY2018



## FY2018 was a year of significant progress for the Company

- Secured four Group Purchasing Organization (GPO) contracts, covering 50% of US heart hospitals
- Successful \$14.3m capital raise to accelerate GPO-focused strategy, including new cornerstone shareholder Allan Gray
- DyeVert featured in ten podium presentations, at six cardiology meetings
- Launched new product DyeVert Plus EZ in November, now ~60% sales mix and growing
- Commenced market access to obtain recommendation for DyeVert from the National Institute for Health and Care Excellence (NICE) in the UK
- Partnered with GE Healthcare, one of the largest suppliers of imaging contrast agent, for the Be Kind to Kidneys™ campaign to build awareness of CI-AKI





## Financial highlights FY2018



## Osprey continues to experience strong unit volume/revenue growth

- FY2018 DyeVert units sold of 7,201 an increase of 57% on the prior corresponding period (pcp)
- Three year compound annual growth rate (CAGR) of **179% for DyeVert**
- FY2018 revenue growth of **54%** to **US\$2.5m**
- Operating expenditures were US\$19.0m, up 22% on the pcp, reflecting an increase in predominately sales and marketing expenses to drive future sales growth
- FY2018 Net Loss after tax of **US\$17.5m**, an increase of **22%** on the pcp
- Closing cash balance of US\$25.2m (US\$20.1m as at 31 March 2019)

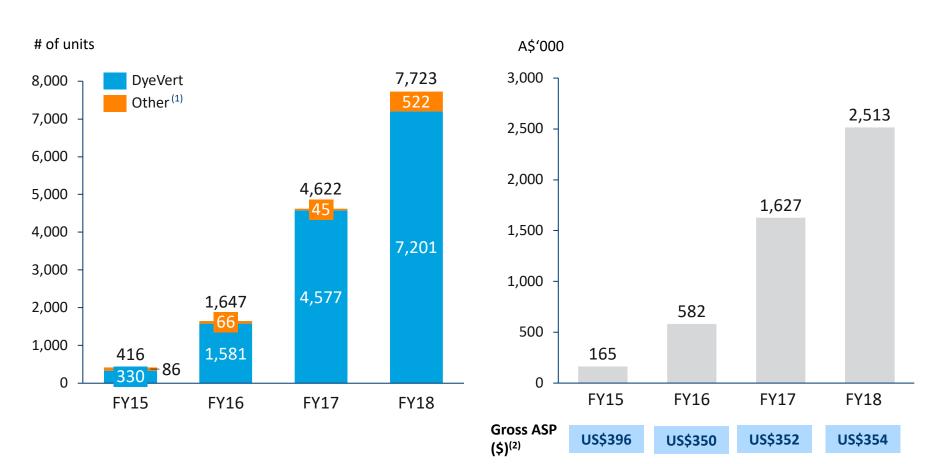
# Financial highlights FY2018 (cont.)



Strong unit growth translated to strong revenue growth, underpinned by stable pricing

### Total unit sales since 2015 (#)

## **Revenue and Average Selling Prices since 2015**



Note.

Other includes DyeTect systems and syringes

# Osprey is dedicated to protecting kidneys



## The problem

# Dye used in common imaging procedures has harmful effects on patients' kidneys

X-ray dye used in common imaging procedures for heart/legs can cause damage known as Contrast Inducted Acute Kidney Injury (CI-AKI)

# CI-AKI can have debilitating and life threatening consequences

Significant body of clinical evidence suggests AKI can result in debilitating and potentially life threatening consequences

CI-AKI in the CKD population undergoing angiography increased from 18% in 2012 to 28% in 2017<sup>1</sup>

## **DyeVert System**

Proprietary technology

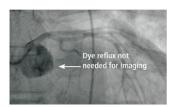
Designed for CI-AKI at risk patients requiring contrast minimization

Easy to use

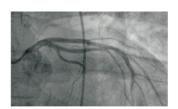
Easy to set up, does not disrupt patient flow and in line with standard physician guidelines

**FDA cleared** 

Only device with an FDA cleared claim for dye reduction without the compromise of image quality



Without Osprey dye reduction

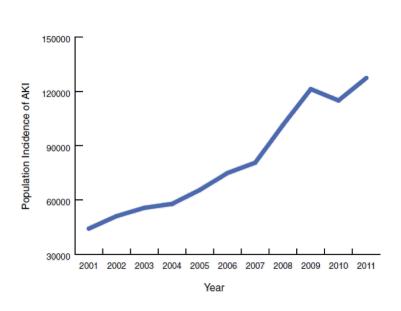


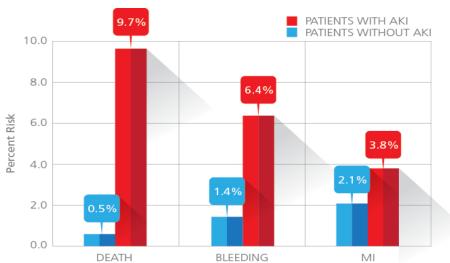
With Osprey dye reduction

## Patient Impact From CI-AKI



# CI-AKI is a growing problem associated with poor patient outcomes after coronary angiography or intervention





AKI incidence: population incidence of acute kidney injury among cardiac cath. and PCI patients in the United States from 2001 to 2011. AKI indicates acute kidney injury. Brown J et al. *J Am Heart Assoc*. 2016;5:e002739.

Tsai TT, Patel UD, Chang TI et al. Contemporary Incidence, Predictors, and Outcomes of Acute Kidney Injury in Patients Undergoing Percutaneous Coronary Interventions: Insights from the NCDR Cath-PCI Registry. *J Am Coll Cardiol Intv* 2014;7:1-9.

# Hospital Impact From CI-AKI



# Hospital costs increase for patients with CI-AKI as most procedure-related poor outcomes are the responsibility of the hospital

1. Increased length of stay<sup>1</sup>

2. Increased 30-day readmissions<sup>2</sup>

3. Increased bundled payment risk<sup>3</sup>



US\$1.7bn Cost of CI-AKI to hospitals each year<sup>4</sup>

<sup>1</sup> Subramanian S, et al. Economic Burden of CIN: Implications for Prevention Strategies. Journal of Medical Economics. 2007;10:119-134.

<sup>1</sup> Pfunter A, et al. Agency for Healthcare Research and Quality Statistical Brief #168. December 2013. https://www.hcup-us.ahrq.gov/reports/statbriefs/sb168-Hospital-Costs-United-States-2011.pdf

<sup>2</sup> Center of Medicare and Medicaid Services Website: http://www.cms.gov/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-ReductionpProgram.html

<sup>2</sup> American Hospital Association Factsheet: Hospital Readmission Reduction Program. April 14, 2014. http://www.aha.org/content/13/fs-readmissions.pdf

<sup>3</sup> American College of Cardiology CMS Releases Proposed 2018 Medicare QPP Rule http://www.acc.org/latest-in-cardiology/articles/2017/06/20/17/40/cms-releases-proposed-2018-medicare-qpp-rule

<sup>4</sup> Prasad, A. et al. 2019. Acute Kidney Injury Incidence, Risk Factors, and Costs Among U.S. Patients Undergoing Percutaneous Coronary Procedures. American College of Cardiology Annual Meeting. Poster Presentation.

## AKI reduction initiatives



## Real-World AKI Prevention Strategies that Work

St. Mary's Medical Center Huntington, WV

Presented at West Virginia ACC 2018 Annual Conference







Houston Methodist Sugarland Hospital Sugarland, TX

Presented at ACC NCDR 2018 Annual Meeting







**University Health System** 

San Antonio, TX

Presented at ACC Quality Summit 2019 Annual Meeting







Metropolitan Methodist Hospital

San Antonio, TX

Presented at ACC Quality Summit 2019 Annual Meeting







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## Osprey's total market opportunity is US\$1.65bn



DyeVert Plus market opportunity of 3.2m procedures per year in the USA and Western EU

CKD: 1.3 million procedures per year

Diabetes: 1.0 million procedures per year

STEMI: 440K procedures per year

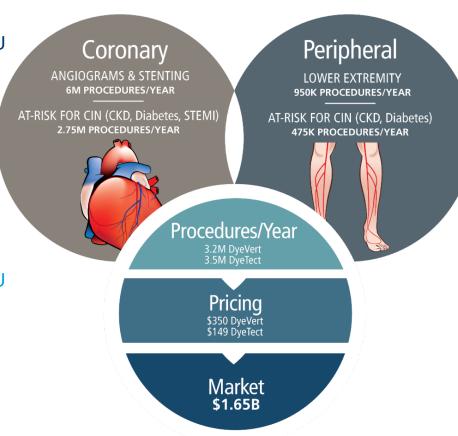
Peripheral: 450K procedures per year

DyeTect market opportunity of 3.5m procedures per year in the USA and Western EU

- Coronary: 3.1 million procedures per year

Peripheral: 476K procedures per year

Average selling price of DyeVert is US\$350



Our FY2018 sales imply <1% penetration – a long term growth opportunity

## Execution of GPO strategy in FY2018



We introduced our National Accounts or GPO Strategy approximately 12 months ago, and since that time we have made significant progress in executing our plan

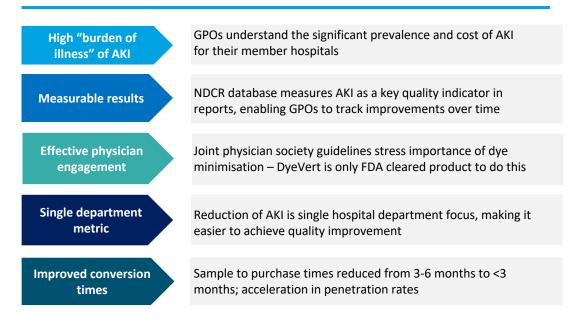
Group Purchasing Organisations (GPOs) represent some of the largest networks of hospitals and health care providers in the US, and have some of the largest global healthcare databases







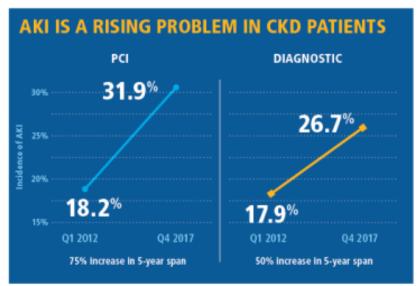
### What is driving Osprey's GPO success?

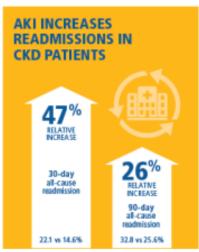


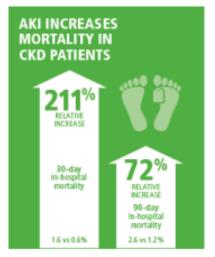
# PREMIER CI-AKI Burden of Illness Study

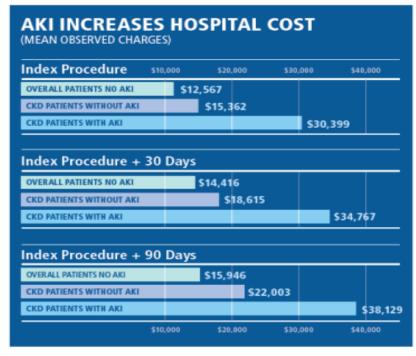


## 700 hospitals with 2.8M angiography patients with CKD 2012-2017









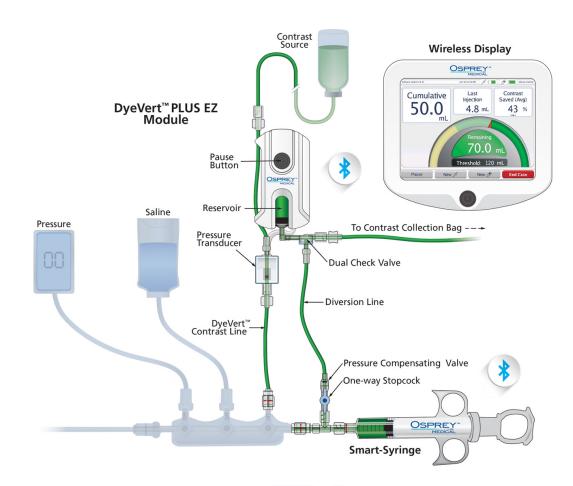


## Our R&D Continues to Deliver Innovative New Products



### **DyeVert PLUS EZ Launch Success in November 2018**

- Intuitive one-way "positive" prime of system reduces set-up type from minutes to seconds
- Easy-to-remember priming, with fewer system components requiring air removal before use
- Diverted amount can be seen in collection bag at the end of the procedure
- Clinician acceptance and adoption has been significant to date (~60% of sales mix in first full quarter and growing)
- Osprey's ability to innovate and respond to clinicians wants and needs has underpinned our growth trajectory





## Osprey sales strategy addresses all key decision makers





Secure national Value Based Agreements

### Osprey is focused on continuing to secure new GPO accounts in FY2019

- Osprey's four contracts cover 50% of all CKD cases in the US
- Osprey continues to pursue additional GPO relationships to further improve coverage
- Focused on building evidence of improved patient outcomes and lower hospital costs



Increase penetration in GPO accounts

# Significant headroom in penetration rates of contracted GPO hospitals in existing sales territories

- Field sales force and clinical support staff focused on hospitals within GPOs, working with hospitals and doctors to standardize care, both to improve AKI outcomes and lower hospital cost
- Adoption based on standard care-pathway protocol for all member hospitals

# PARTNER RESEARCH

Cement relationship and drive adoption

# Ongoing investment in GPO-supported studies to build GPO-level relationships and support adoption in member hospitals

- Osprey is partnering with GPOs to support outcome-based purchasing models
- Recently published 'Burden of illness' study with leading US GPO, Premier
- Launched partnered education program with GE Healthcare on AKI awareness

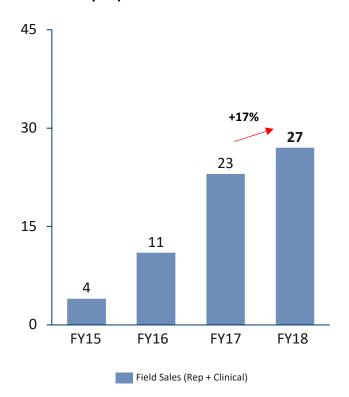
## Sales territories

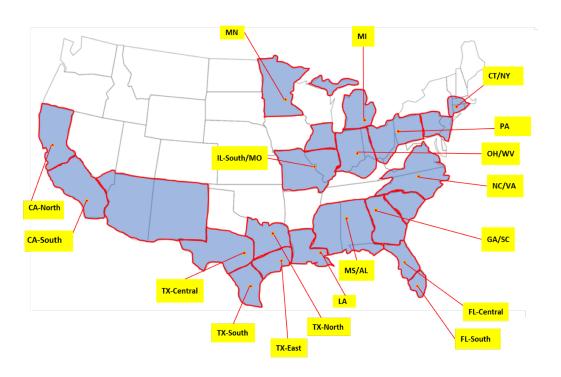


### Osprey's sales force effectiveness materially improved in FY2018

- Headcount expansion of 17% delivered sales growth of 54%, driven by:
  - Focus on hospitals covered by an existing GPO contract
  - Increased unit order size per account increased 33%
  - Average unit sales per salesperson increased 39%

#### # of sales people







## Solid first quarter delivered, driven by continued momentum at GPO level

### **Key highlights**

#### In 1Q2019, Osprey achieved:

- 18<sup>th</sup> consecutive quarter of growth
- DyeVert unit sales up 73% over the pcp
- Revenues up 56%, reflecting increased mix of GPObased sales (62% vs. 40% in pcp)
- GPO-based sales up 158% to 1,374 units
- 23% increase in new purchasing hospitals
- 20 hospitals in sample-to-purchase pipeline

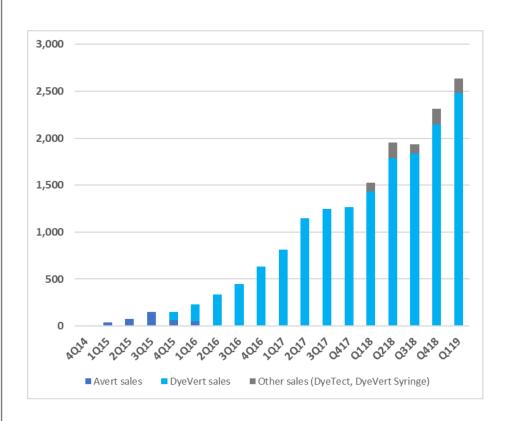
# Significant clinical data presented at ACC and ACC Quality Summit

 Four presentations highlighting increased incidence of CI-AKI and benefit of contrast dye minimization strategies with DyeVert on patient outcomes

### Appointment of Mr Jim Surek as VP, Sales

Substantial (25 years) commercial experience

### Quarterly product unit sales since inception



# The DyeMINISH™ Registry







### **DyeVert System Use for Contrast Monitoring and Minimization in At-Risk Patients Undergoing Angiography Procedures: A Real-World Registry**

- Provide Osprey with strong real-world evidence
- Highly cost-effective study design versus randomised controlled clinical study
- Synergies with sales model (commercial DyeVert use patients included in the registry)



### Observational, retrospective, large-scale, multi-centre study

- Core Study Cohort: evaluate the use of imaging dye thresholds, actual imaging dye delivered to the patient and imaging dye saved
- Comparative Study Cohort: compare the difference in health outcomes in patients who received DyeVert versus similar patients without DyeVert through 120 days post procedure
- Up to 10,000 participants, study completion expected prior to the end of 2023



#### Critical real-world evidence

- Important for healthcare and regulatory decision making, policy development, clinical guidelines and payor coverage
- Support peer-reviewed publications and education/awareness build-out
- Improving clinical care for Chronic Kidney Disease patients undergoing angiography procedures

# Outlook: Osprey remains firmly focused on sales to drive shareholder returns



# **GPO SALES STRATEGY**

Driving increased adoption

- Continued growth in unit sales and accounts in 2019
- Providing future market opportunities and creating a broad 'top down' sales platform for increased adoption
- Originate new GPO distribution agreements in expanding hospital network footprint

# EXPANSION INTO NEW MARKETS

Initial focus on Western Europe

- Pilot sales and enter into Western Europe (UK and Italy)
- Continue to build brand awareness of DyeVert production outside of the US

#### **PUBLICATIONS**

Publications and podium presentations drive awareness

- Continue to publish clinical results to drive increased interest and adoption among clinicians
- Strong presence at upcoming SCAI and Premier Breakthroughs meeting
- Several new scientific studies on DyeVert/AKI to be presented

# INCREASE PENETRATION

Increasing penetration in all regions

- Increase average order size and penetration across all sales territories
  - **DyeVert Plus EZ** simplified setup and operation focused on increase usage by physicians and Cath Lab staff





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DyeVert™, DyeVert Plus, DyeVert Plus Ez and DyeTect Systems Regulatory Status: Europe – CE Mark obtained; Australia – TGA approval obtained; United States – 510(k) cleared.