

**ASX ANNOUNCEMENT – 2016 Annual Meeting of Stockholders  
– Chairman’s Address and Presentation by President and CEO**

**Melbourne, Australia and Minnesota, United States – May 12, 2016** – Osprey Medical Inc. (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 2016 Annual Meeting of Stockholders at Johnson Winter & Slattery’s Melbourne office, Level 34, 55 Collins Street, Melbourne, Victoria, Australia on Thursday, 12 May 2015 at 9.00am Australian Eastern Standard Time (Wednesday, 11 May 2015 at 6.00pm U.S. Central Time).

Brendan Case  
Australian Secretary

**About Osprey**

Osprey Medical is focused on protecting patients from the harmful effects of X-ray dye (contrast) used during commonly performed angiographic imaging procedures. The Company’s core technologies originated from research conducted by Dr David Kaye at Melbourne’s Baker IDI Heart and Diabetes Institute. Its proprietary dye reduction and monitoring technologies are designed to help physicians minimize dye usage. The Company’s DyeVert™ System is a next-generation product that reduces contrast while maintaining image quality in a self-adjusting easy-to-use design. 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.

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Chairman's address

AGM - May 12, 2016

John Erb

Good morning ladies and gentlemen,

My name is John Erb, Chairman of your company Osprey Medical.

It is now 9.00am and I note that this is a properly constituted meeting and I have been advised that a quorum is present for the matters to be considered at this meeting. I therefore declare this Annual Meeting of stockholders of Osprey Medical open and welcome each of you.

First of all I'd like to introduce you to our President and Chief Executive Officer Mike McCormick. Along with Mike we have our directors who I will also ask to stand as I introduce them.

We have Andy Jane, Neville Mitchell and Chris Nave.

The notice of meeting has been sent to shareholders and I'll take it as read. The annual report details the company's progress over the past 12 months.

And what progress it's been!

We have seen the development of the DyeVert, our second generation upgrade of the AVERT System. It's a device that we're very excited about and the promise that it holds.

It's smaller and simpler to use and has greater dye savings. And the feedback we're getting from doctors has been outstanding.

The DyeVert will become our lead product and we believe it will also become the standard of care for physicians treating patients with kidneys at risk of dye damage.

The device has also been featured at the most recent Society for Cardiovascular Angiography and Interventions Meeting last week in Orland Florida, where dye savings of 49% was noted.

We're already seeing strong sales of DyeVert and we expect them to grow rapidly as we employ more sales representatives and implement our proven commercialisation strategy.

We have initially focused on the southern states of the US, where there is the greatest incidence of acute kidney injury and where reducing exposure to x-ray dye during procedures is most needed. But this year we expect to broaden our market footprint and expand into other regions.

It's also exciting that we received FDA clearance for a number of marketing claims for our AVERT system, which have also been cleared for DyeVert.

Osprey is now in the enviable position of being the only company with devices in the market cleared by the FDA for contrast volume reduction.

It also means we're the only product that addresses cardiology and radiology treatment guidelines that call for minimal dye dose in renal-impaired patients.

During SCAI, Professor Roxana Mehran presented the clinical study results from our AVERT Trial. The Trial showed that AVERT reduced the amount of contrast volume delivered by 15% overall and by 23% in PCI or Stent procedures, while maintaining adequate image quality. The study did not result in a significant reduction of CI-AKI, however a post-hoc sub-group analysis shows a significant reduction (-49.5%) in CI-AKI in patients with eGFR 40-60 ml/min which represents a large segment of our market. The immediate response from many Physicians attending the meeting was positive as Osprey's trade show had consistent Physician interest in the system. We feel that the AVERT Trial results that allowed us to achieve a FDA marketing claim for dye volume reduction, along with the data showing a strong trend of how contrast reduction can impact CIN will help us continue to drive further commercial success in 2016.

Our dye reduction platforms are an example of our commitment to creating products that make a difference in the lives of patients and that help physicians and hospitals provide the best treatment possible.

Our mission remains helping to protect patient's kidneys from the harmful effects of x-ray dye with devices that reduce the amount of dye used during heart procedures without affecting image quality.

It's a mission we're proud to embrace and one we believe will deliver many opportunities and rewards for a long time.

I'd like to thank Mike and his management team for all their efforts over the past 12 months and look forward to the year ahead.

I'd now like to call upon Mike to outline our priorities for the year ahead.

Thanks Mike.



# AGM presentation

12 May 2016

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MEDICAL

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[All figures in the presentation are A\$ thousands on a constant currency basis based on an exchange rates of A\$1: US\$[ ] unless stated otherwise and all market shares are estimates only. The pro-forma historical financial information included in this presentation does not purport to be in compliance with Article 11 of Regulation S-X of the rules and regulations of the US Securities and Exchange Commission. This presentation may contain certain financial data that is "non-GAAP financial measures" under Regulation G under the U.S. Securities Exchange Act of 1934, as amended. The disclosure of such non-GAAP financial measures in the manner included in this presentation would not be permissible in a registration statement under the Securities Act. These non-GAAP financial measures do not have a standardised meaning prescribed by AIFRS and, therefore, may not be comparable to similarly titled measures presented by other entities, nor should they be construed as an alternative to other financial measures determined in accordance with AIFRS. Although we believe these non-GAAP financial measures provide useful information to users in measuring the financial performance and condition of our business for the reasons set out in this presentation, you are cautioned not to placed undue reliance on any non-GAAP financial measures and ratios included in this presentation.]

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

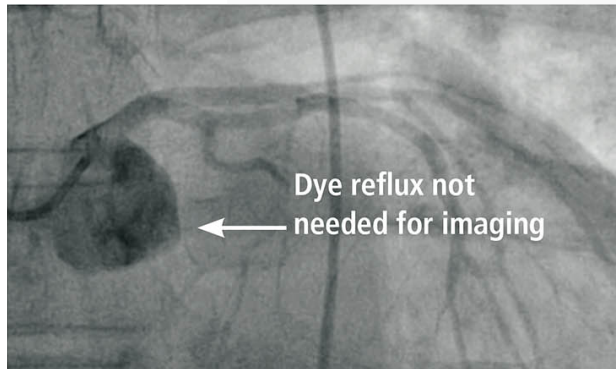
# **Mr Mike McCormick, President & CEO**

**Address to the 2016  
Annual Meeting of Stockholders**

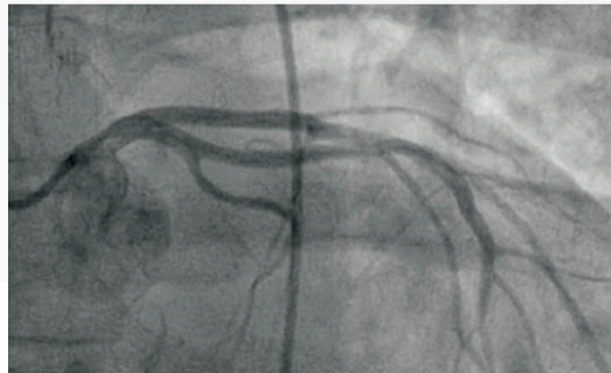
# Osprey – protecting patient kidneys from dye

Osprey is a revenue stage company with proprietary medical device technology designed to protect patient kidneys from dye

- Heart and leg vessels imaging (x-ray) requires the injection of x-ray dye which is then cleared by the kidney
- Osprey is a medical devices company with **proprietary technology** designed to **reduce the amount of contrast dye injected** during these commonly performed procedures, to protect the kidneys from damage



Without Osprey dye reduction



With Osprey dye reduction





# Product portfolio



*Randomized Control  
Clinical Study*



*Commercialized*



*Commercialized*




*Under Development*



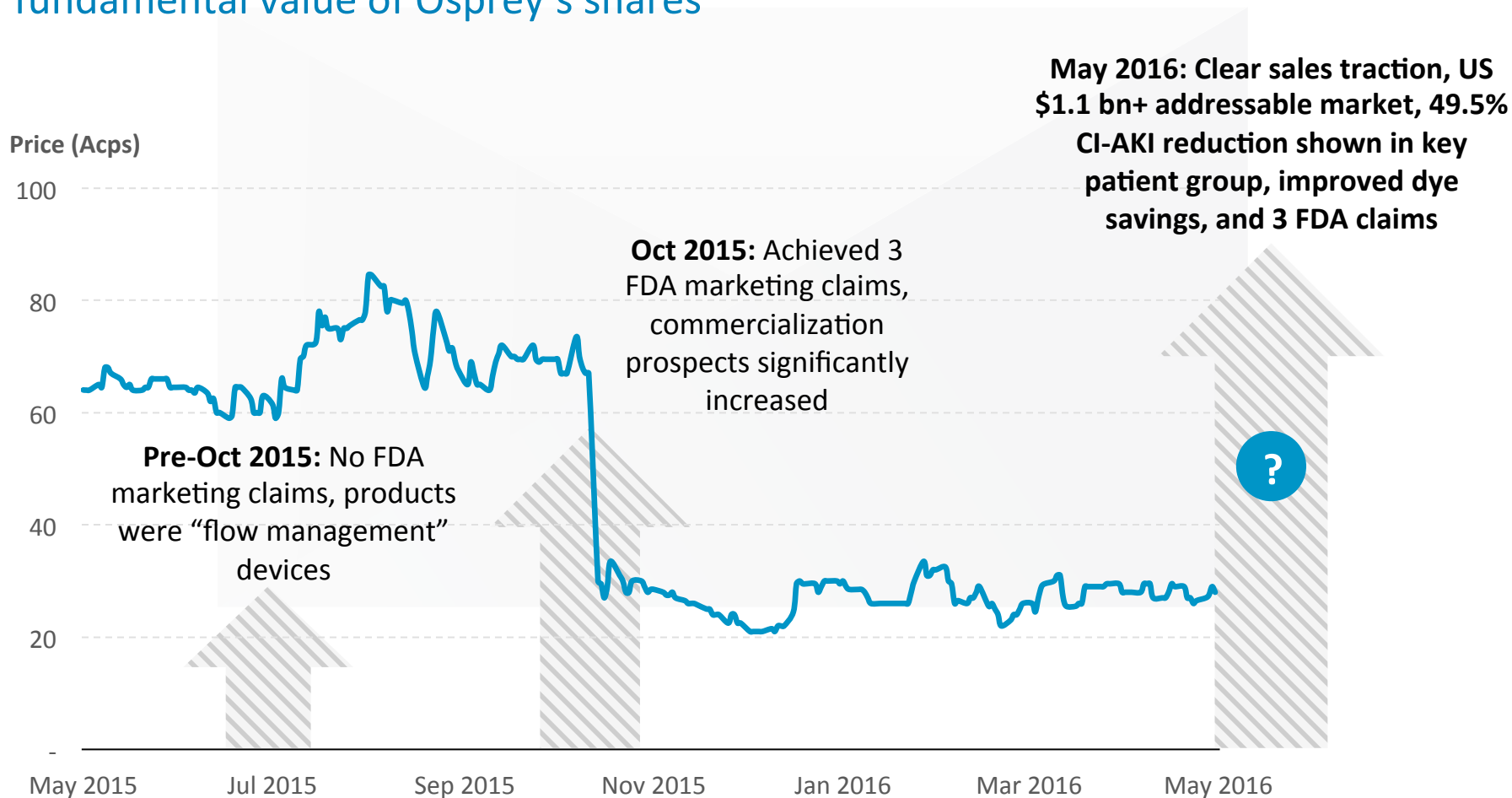
# 2015: Year in review

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1. Complete enrolment in the AVERT post market clinical/economic trial expected mid-2015
  2. FDA submission for dye savings, reflux reduction and image quality claims in Q4 2015
  3. Validate AVERT sales adoption model in preparation for sales force expansion of up to 20 US reps by end of CY 2016
  4. Accelerate market awareness of the dangers of dye and advantages of lowering dye administration with the AVERT and DyeVert Systems
  5. On going R&D efforts continue to enrich Osprey's product pipeline

# Valuation disconnect

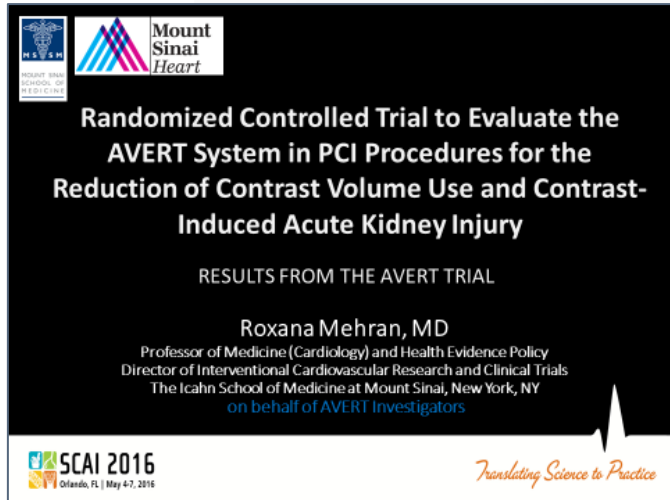
Ongoing clinical and operational achievements continue to enhance the fundamental value of Osprey's shares



# AVERT clinical trial results presented at SCAI



The AVERT results were presented as the first scientific presentation at one of the world's largest gatherings of heart physicians and professionals<sup>1</sup>



## Dr Roxana Mehran, MD

AVERT Principal Investigator

The study's Principal Investigator, Dr. Roxana Mehran, is a U.S. interventional cardiologist with world-recognized expertise in the area of CIN. She is Professor of Medicine and Director of Interventional Cardiovascular Research at Mount Sinai Hospital in New York.

<sup>1</sup> Dr. Mehran's Presentation is available on [www.ospreymed.com](http://www.ospreymed.com)

# Primary analysis: Dye volume & kidney function

## Statistical significant reduction in contrast leads to 3 FDA marketing claims

- FDA Claims – Dye savings, image quality, reflux reduction
- A reduction in Contrast Induced-Acute Kidney Injury (CI-AKI) was not observed, however using the standard definition of CI-AKI (0.5mg/dL or  $\geq 25\%$ ) a **clinically relevant reduction was observed warranting further analysis**

### Contrast Volume Reduction – Primary Results

	Control (N=284)	AVERT (N=283)	Relative Reduction (AVERT vs. Control)	P-value based on t-test <sup>1</sup>	P-value based on Wilcoxon	P-value based on log transformation
CV (ml)	101.3 $\pm$ 71.1	85.6 $\pm$ 50.5	<b>15.5%</b>	0.0024	0.0349	0.0218

### Kidney Function – Primary and Pre-specified Secondary Results

SCr increase	Control N= 282	AVERT N= 281	% Change	Odds Ratio - (95% CI)	P-value
$\geq 0.3\text{mg/dL}$	74/282 (26.2%)	76/281 (27.0%)	3.1%	1.042 (0.717, 1.514)	0.7235
0.5mg/dL or $\geq 25\%$	47/282 (16.7%)	43/281 (15.3%)	<b>-8.2%</b>	0.903 (0.575, 1.418)	0.3721 <sup>3</sup>

1 Based on one-sided tests using Fisher's combination method and a 0.025 alpha level

2 P-value based on one-sided Fisher's exact test; alpha level of 0.025 and Fisher's combination method

3 P-value based on one-sided Fisher's exact test; alpha level of 0.025

# Importance of Physician Steering Committee

A crucial part of the clinical trial process is the Physician Steering Committee direction of additional analysis

1. Full analysis using the “standard definition” for CIN (Serum Creatinine increase of  $\geq 0.5\text{mg/dL}$  or  $\geq 25\%$ )

“The trial was conducted using FDA directed criteria (an increase by  $\geq 0.3\text{mg/dL}$ ), however we also looked at “standard criteria” because this captures significant, permanent changes in kidney function and is what we’re used to as physicians”

**Dr. Roxana Mehran, MD**

2. Per protocol analysis - excluded patients where protocol deviations occurred that may have affected kidney function:

1. Baseline kidney function measured > 72 hours prior to procedure
2. Hydration started prior to baseline kidney function measurement
3. Hydration protocol not followed
4. Contrast used outside coronaries (>10 mL) at procedure or within 5 days

# Analysis of dye reduction

Post-trial per-protocol analysis showed a statistically significant reduction in contrast volume

- Physician Steering Committee analysis showed increased dye savings in stenting procedures
- Dye savings of up to 46%** in more complex cases requiring multiple stents

Contrast Volume Reduction			
	Control	AVERT	Dye saved
All Patients	99.1 ± 71.8	83.1 ± 48.8	16.2%
PCI/Stenting – 1 vessel	126.8 ± 63.3	108.3 ± 55.2	14.6%
PCI/Stenting – 2 vessels	188.0 ± 99.3	130.4 ± 53.5	30.6%
PCI/Stenting – 3 vessels	231.5 ± 96.7	124.0 ± 47.9	46.4%

# Analysis of kidney damage

Post-trial per-protocol analysis showed a statistically significant 49.5% reduction in CI-AKI in a key patient group with AVERT

- Post trial per-protocol analysis showed a **statistically significant 49.5% reduction in CI-AKI in patients with pre-existing stage 3 kidney disease**
- Stage 3 kidney disease refers to patients who have lost half or more of their normal kidney function
- This patient group is Osprey's primary market focus and it is extremely encouraging to see such a strong response in this group

CI-AKI Reduction					
		Control	AVERT	Relative reduction	P-value
All Patients		41/230 (17.8%)	34/240 (14.2%)	20.5%	0.1693 <sup>1</sup>
PCI (N=202)		19/96 (19.8%)	15/106 (14.2%)	28.5%	0.3474 <sup>2</sup>
Diagnostics (N=268)		22/134 (16.4%)	19/134 (14.2%)	13.6%	0.7347 <sup>2</sup>
Patients with pre-existing stage 3 kidney disease (N=264)		29/135 (21.5%)	14/129 (10.9%)	49.5%	0.0204 <sup>2</sup>

1 P-value based on one-sided Fisher's exact test; alpha level of 0.025

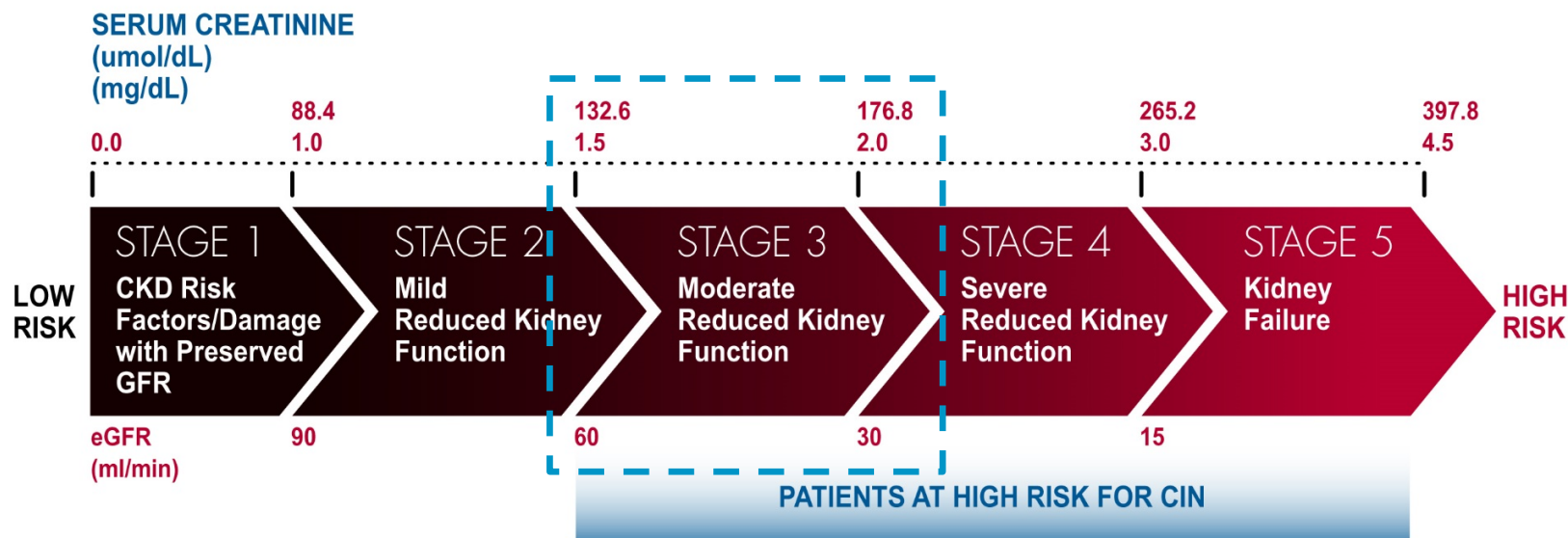
2 P-value based on two-sided Fisher's exact test



# Market opportunity

## Positive trial results and FDA claims to drive commercialization

- Patients with Stage 3 to 5 kidney disease are classified as having Chronic Kidney Disease (CKD)
- DyeVert is targeted at patients with pre-existing CKD with Stage 3 kidney disease (eGFR 40-60), which represents more than 75% of all poor kidney function patients
- **1.3 million CKD procedures per year in US and Western EU**
- **Number 1 procedure out of Osprey's total market opportunity of 3.2 million procedures**



\*Serum creatinine measures in the figure are approximations

# AVERT clinical trial results summary

Received 3 FDA marketing claims and clinically significant reduction in CI-AKI

- Oct 2015** 3 FDA marketing claims received early: dye savings, image quality and reflux reduction with no difference in CI-AKI. Physician steering committee review had not commenced
- Dec 2015** Physician steering committee directed per-protocol analysis using the “standard criteria” (Serum Creatinine increase of  $\geq 0.5\text{mg/dL}$  or  $\geq 25\%$ ) showed improved dye savings of up to 46% in more complex cases and clinically relevant reduction in CI-AKI
- Dec 2015 to May 2016 the data sequestered for publication at SCAI meeting**
- May 2016** Post-trial per-protocol analysis revealed a non-statistically significant but clinically relevant 20.5% reduction in CI-AKI in all patients and a 49.5% significant reduction for patients with stage 3 kidney disease

DyeVert a next generation product which is easier to use and saves more dye



## Easier to use

- Self adjusting (automatic) for different catheter configurations
- Set-up and priming does not interfere with flow

## Increased dye savings

- 49.0% dye savings reported at SCAI
- Saves contrast even on puffs
- Saves contrast without requiring user adjustments

## No box control

- All disposable/no hardware outside of sterile field

## February 2016 FDA Claims Announcement

### DyeVert FDA claims received

- Dye savings
- Image quality
- Reflux reduction

# DyeVert clinical trial results shared at SCAI

DyeVert demonstrated significant dye savings of 49% which should support ongoing commercialization efforts throughout the US

## Dr Anand Prasad

Assistant Professor of Medicine, University of Texas

“DyeVert demonstrated **dye savings of 49%** with uncompromised image quality. The fully disposable, hands free system is **easy to use and saves more dye**. The reaction from the physician community at SCAI was very positive”



Study groups	Attempted (Average mL's)	Actual to Patient (Average mL's)	Dye Saved (Average mL's)	% Dye Saved (Average)
<b>All (N=69 patients)<sup>1</sup></b>	<b>171.6</b>	<b>86.8</b>	<b>84.7</b>	<b>49.0%</b>
PCI/Stenting (N=16)	356.0	182.9	173.2	49.5%
Diagnostic (N=50)	109.2	54.3	54.8	48.5%

<sup>1</sup> Three peripheral angiograms included

# DyeVert product development

Osprey is developing DyeVert Plus which features real-time tracking of dye use throughout the procedure

**DYEVERT<sup>TM</sup>**  
Contrast Modulation/Monitoring System  
**PLUS**

✓  
**Complies with  
new US  
cardiology  
guidelines**

- **Real-time volume threshold monitoring** of dye delivered to the patient during the procedure
- **Accurate dye dosage documentation** to help comply cardiology guidelines

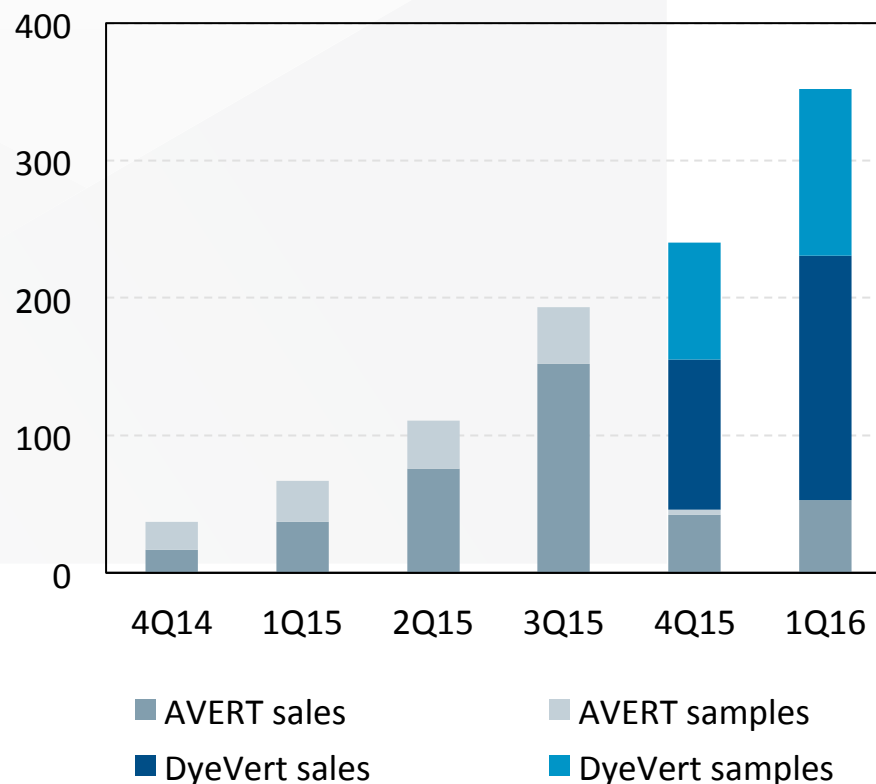


# Sales growth

## Sales traction evidenced by clear product-market fit and strong customer growth

- Osprey has achieved **6 consecutive quarters of growth** in units sold and sampled since the first customer sale
- **Units sold growth of 53%** for DyeVert and AVERT in 1Q 2016 compared to 4Q 2015
- **Sales revenue grew by 42%** in 1Q 2016 compared to 4Q 2015

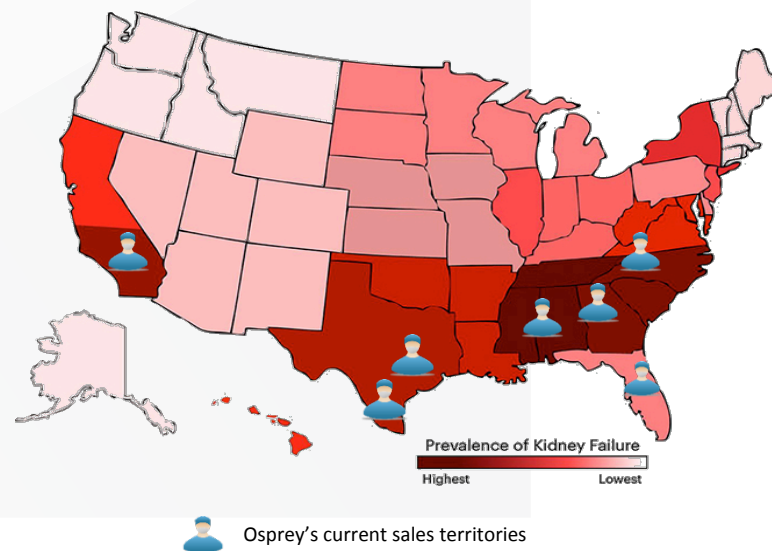
Quarterly product unit sales & sales since inception



# Commercialization update

## US commercialization of DyeVert has recorded faster than expected adoption rates

- **A record number of new hospitals** have purchased or are conducting evaluations on the DyeVert System
- 7 sales reps are now marketing Osprey's suite of products, **with 2 additional reps to be added this quarter**. On track to reach 20 sales reps by end of CY 2016
- Sales territories include Alabama, Georgia, Florida, Mississippi, North and South Carolina, Southern California, Texas and Virginia. New territories to be added this quarter, Miami FL and Dallas TX
- New territories expected to be those with highest incidences of kidney failure





# Economically effective

US healthcare payment reform has created an economic incentive for Osprey's products

- The Patient Protection & Affordable Care Act 2010 ("ObamaCare") has changed the economic landscape for medical care in the US **creating a favorable economic climate for Osprey's technology**
- ObamaCare has redefined hospital and physician payment structures so that **payment will be based on quality metrics rather than volume**
- **Dye volume and CI-AKI are key quality metrics** under ObamaCare according to the National Cardiovascular Data Registry
- **Economic penalties can apply to hospitals that do not comply with ObamaCare**



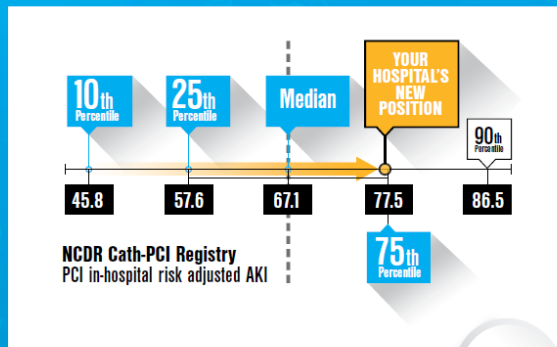
CathPCI Registry<sup>®</sup>

# Osprey's marketing message

Osprey is taking advantage of the national changes to drive market awareness and product adoption

**Is your hospital's AKI score  
higher than the NCDR  
national median?**

*Ask how Osprey can help.*



**HAVE A HEART, BE KIND TO KIDNEYS**  
CATH LAB KIDNEY CARE **PROTOCOL**

OSPREY<sup>™</sup>  
MEDICAL

**DYEVERT<sup>™</sup>**  
Contrast Modulation System

*Proven Contrast Savings With  
Uncompromised Imaging*

**For At-Risk Patients**  
The only FDA indicated technology  
for contrast volume reduction

**HAVE A HEART,  
BE KIND  
TO KIDNEYS**

CATH LAB KIDNEY CARE **PROTOCOL**

- ♥ SCREEN FOR RISK
- ♥ INCREASE HYDRATION
- ♥ REDUCE CONTRAST

# Business Focus 2016

## Osprey's key focus is sales growth

### **SALES GROWTH**

*Grow sales team and territories*

- Ongoing quarter on quarter sales growth expected as new sales reps develop relationships in new territories
- A larger sales team is expected to drive further sales growth

### **R&D**

*Development of R&D portfolio*

- Enhancements are being made to DyeVert to create DyeVert Plus, which records savings in real-time
- FDA approval for DyeVert Plus expected in 2H 2016

### **DYEVERT**

*Presentation of trial results*

- Multi-center DyeVert clinical trial results to be presented at the EuroPCR in May 2016
- DyeVert RCT enrolling, findings are expected to be presented in 2016

### **ECONOMICS**

*Capitalize on new legislation*

- Capitalize on the shift of hospital/physician payments based on "procedure volume" to "improving quality"
- Take advantage of mandatory dye savings guidelines

# Executive staff and BoD

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Doug Schoenberg  
VP Marketing



Rod Houfburg  
VP R&D



Vic Fabano  
VP Ops & Quality



Nancy Ness  
VP Finance



Michele Shepard  
VP Clinical



Hank Butcher  
VP Sales



Melanie Hess  
VP Regulatory



John Erb  
Chairman



Neville Mitchell  
Director



Andy Jane  
Director



Chris Nave  
Director

# Thank you.

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