13TH EDITION

## INVESTOR NEWSLETTER



MIKE MCCORMICK

#### Dear Shareholders.

The start of 2016 has been an exciting time for Osprey as we ramp up US commercialisation of the DyeVert<sup>™</sup> System and see our technology featured prominently at some of the world's leading medical conferences.

Key highlights from the year to date:

- 1. Commercialisation accelerating with 8 sales representatives to increase to 20 by year end;
- 2. Original sales territory in San Antonio, Texas has over 57% of hospitals purchasing and 39% penetration of Chronic Kidney Disease patients;
- 3. Q1 revenue grew 42% quarter-overtrailing quarter and 414% quarter-overprevious year;
- 4. Sales accelerating with DyeVert due to its ease of use and increased dye savings over AVERT;
- 5. AVERT post-trial subgroup analysis revealed 49.5% reduction in kidney damage among key patient group;
- 6. Trial of next-generation DyeVert system shows 47.4% reduction in contrast dye usage:
- 7. The advantages of Osprey's dye-savings technologies presented at 3 key Cardiology medical conferences;
- 8. Dr. Brar, Kaiser Permanente Los Angeles, California commented on AVERT™ trial podium presentation, "The volume of dye is strongly associated both with morbidity and mortality in renal insufficient patients; this trial shows the utility of the AVERT system at reducing dye volume and the sub group analysis shows promising CI-AKI reduction.'

After receiving FDA marketing claims for dye savings and image quality, we started scaling our US sales efforts with the addition of 5 new sales representatives hired in December 2015. To date, we have 8 sales representatives with plans to hire 12 additional by the end of CY 2016 for a total of 20 sales territories. Our most recent rep was added this month in Miami.

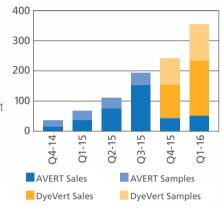
A key indicator of sales success is market share penetration of Chronic Kidney Disease (CKD) patients in hospitals where the AVERT Plus or

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### **Strong Customer Adoption Accelerates Growth**

Osprey had a successful start to 2016, as evidenced by six consecutive quarters of units sold and sample growth since the Company recorded its first customer sale. This has been driven by strong endorsement from the cardiovascular physician community and significant ease-of-use benefits from the DyeVert System. Osprey is proud to report that over 1,800 patients have benefited from our dye-savings technologies.

Q1 revenue grew 42% guarter-over-trailing quarter and 414% quarter-over-previous year. Units sold grew for DyeVert and AVERT by 53% in Q1 2016 compared to Q4 2015.



A leading indicator of future revenue growth is the number of sample evaluations. Sample evaluations of the DyeVert System also experienced significant growth with 121 units recorded for Q1 2016, up 42% from Q4 2015. The growth of DyeVert samples is reflective of multiple new physicians eager to evaluate this next-generation technology. Conversion rates of hospitals upgrading from DyeVert samples to initial product orders remains high at approximately 85%, reflecting the quality of the product in enabling an improved standard of care for patients. Time from sample evaluation to initial orders averages 4 months, which reflects the timelines surrounding the US hospitals Value Assessment Committee (VAC) evaluation and demonstrates a reduced timeline compared with AVERT. Strong take-up of new orders is combined with consistent usage from existing customers making routine re-orders.

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### SCAI Features AVERT Trial Results

Results of the AVERT Clinical Trial were presented at the Society for Cardiovascular Angiography and Interventions (SCAI) annual meeting on May 4, 2016. The SCAI meeting is one of the world's largest gatherings of heart physicians and professionals delivering the latest developments and innovations in the field. Highlighted as a Late Breaking Clinical Trial, the AVERT 578-patient study was presented as the first scientific presentation of the meeting.

Reported key trial aspects emphasized kidney damage reduction (Contrast-Induced Acute Kidney Injury: CI-AKI), dye reduction, as well as uncompromised image quality.

A key focus was the Post-Trial Analysis directed by the Physician Steering Committee on the CI-AKI co-primary endpoint of the trial. Presented by Program Chair and AVERT Clinical Trial Principal Investigator, Dr. Roxana Mehran, the analysis showed a significant reduction of CI-AKI in patients with pre-existing stage 3 kidney disease. Using the "standard criteria" for detection of CI-AKI (Serum Creatinine increase of  $\geq$  0.5mg/dl or  $\geq$  25%), a per-protocol analysis of 470 patients revealed:

Study groups	CI-AKI average reduction	
All Patients (N=470)	20.5%	
Diagnostic (N=268)	28.5%	
PCI/Stenting (N=202)	13.6%	
Pre-existing stage 3 kidney disease (N=264)	49.5%*	

<sup>\*</sup>Denotes significant finding

Stage 3 kidney disease refers to the loss of half or more of normal kidney function. This patient group represents Osprey's primary market focus.

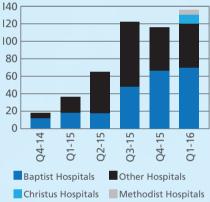
Post-trial analysis also showed AVERT facilitated higher dye reduction – up to 46% – in PCI/Stenting procedures in relation to increased procedure complexity.

#### Shareholder Update Continued..

DyeVert System are purchased. San Antonio, Texas was where we piloted our commercialisation efforts and we have sales history for 6 consecutive quarters (Q4 2014 to Q1 2016). This territory provides the greatest insight into physician take-up of Osprey's dye-savings products. Pleasingly, we have seen an increase in hospital purchases with the new DyeVert System and encouraging market share growth, highlights as follows:

- We have 13 hospitals purchasing our products in San Antonio, which represents 57% of all hospitals;
- Since the launch of DyeVert in November 2015, we have 5 new hospitals purchasing our products:
- Physicians have used DyeVert or AVERT Plus on 487 CKD patients, representing 39% of all CKD patients treated in these 13 hospitals;
- Further revenue growth is expected, with DyeVert evaluations currently taking place in 4 additional San Antonio hospitals;
- Recent traction in the Methodist Health Care System, the largest in San Antonio, indicates further growth potential.

#### San Antonio Hospitals, Total Unit Volume 487



A key component to our commercialisation strategy is to have our technology featured at the podium by key opinion-leading physicians at scientific meetings. Osprey's technology was featured on the podium at three key meetings in the last 90 days:

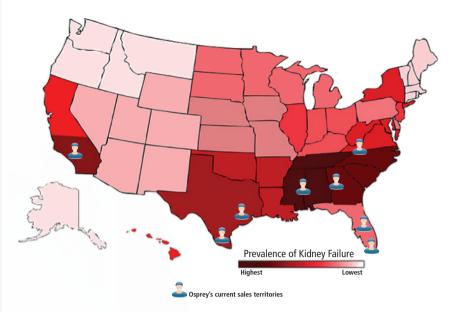
- SCAI presentation of AVERT clinical trial results and a presentation on DyeVert during a special breakfast symposium focused on protecting CKD patients;
- Cardio Renal Connections meeting presentation of the DyeVert System;
- EuroPCR presentation of multi-center trial of the DyeVert System.

Podium presentations increase awareness of our technology within the physician community, and publications expand the scientific understanding of the utility of the AVERT and DyeVert System. In this newsletter you will find details of these meetings and their importance to our selling efforts.

The period has been an exciting and successful one for the Company and we are pleased to report such rapid commercial progress. I would like to thank the employees of Osprey for their passionate pursuit of therapies to reduce the risk of dye-induced kidney damage and to you, our investors, for your continued support.

### Mike McCormick

Mike McCormick, Osprey Medical President & CEO Strong Customer Adoption Accelerates Growth Continued...



We continue scaling our US sales force to commercialise the DyeVert Systems. To date, we have sales reps in 8 territories and have plans to hire up to 12 additional reps in new territories for a total of 20 reps expected by year end. We target new sales reps in the deep south of the US where the incidence of CKD is the highest. Our next targeted areas for sales expansion are Dallas, Kansas City, Chicago and San Francisco.

The sales approach for Osprey's reps is to show the peer reviewed and podium presented data on +45% dye savings with the DyeVert. We position the product for patients at the highest risk of CKD due to their pre-existing poor kidney function. Sales reps provide initial samples so physicians can experience the ease of use, dye savings and uncompromised image quality

of the DyeVert System. Compelling economic advantages exist for hospitals to reduce CI-AKI as this is considered by payers as a hospital-acquired condition and kidney complications following the angiogram (stent or diagnostic) procedure are not reimbursed. Osprey has an 85% conversion rate of hospitals who sample to purchase the product.

To see a product demonstration of the DyeVert System, refer to:

http://www.ospreymed.com/products-dyevert.php

## Kidney Program Reports DyeVert Benefits

SCAI's Satellites Events included a specific program titled Contrast-Induced Acute Kidney Injury: Focus on Hydration and Dye Saving. This dealt with aspects such as incorporating dye savings protocols for patients, practical applications and the future of Acute Kidney Injury regarding contrast. The presentation clearly linked dye savings with reduced instances of CI-AKI.

The DyeVert System was featured at this event on May 5, discussing contrast reduction methods in an effort to address CI-AKI.

Dr. Anand Prasad, University of Texas Medical Center San Antonio, presented results from over 40 patients treated with the DyeVert System.

Dr. Prasad noted that DyeVert demonstrated dye savings of 49% with uncompromised image quality. He presented that the DyeVert System is easy to use and saves more dye than the first-generation AVERT system.

Additionally, Dr. Prakash Balan, University of Texas-Houston, reported on the importance of managing patients susceptible to CI-AKI, since hospital quality metrics track results.



Dr. Prakash Balan, University Texas-Houston, discusses dye savings protocol for high-risk patients.

Given the US healthcare system's substantially greater scrutiny on patient outcomes, Osprey's technologies are well situated as hospitals evolve standard-of-care practices.

## SCAI Updates Best Practices with Contrast Management Focus



#### Best Cardiac Cath Lab Practices Guidelines Published

In early May, SCAI published an update to its best practice guidelines in the cardiac cath lab. The paper, "SCAI Expert Consensus Statement: 2016 Best Practices in the Cardiac Catheterization Laboratory," was released online in *Catheterization and Cardiovascular Interventions*. SCAI's official journal.

Developed by expert practicing interventional cardiologists, the document provides and expands existing cath lab guidelines to ensure the highest quality of care and ultimately better patient outcomes. The paper includes pre-, intraand post-procedure recommendations.

Of particular note was the heightened focus on contrast management of CKD patients, for which Osprey's technologies address:

- Minimising contrast dose is consistently shown to reduce risk of CI-AKI;
- Total contrast administered must be monitored in real time and limited as much as clinically possible;
- Cath lab staff should inform physicians when limits (dose based on contrast volume/kidney function ratios) have been reached.

SCAI's industry guidance continues to be the premier source of patient management direction, adopted widely by physicians and hospitals alike.

These updated guidelines are heavily relied on by physicians and should significantly help Osprey's commercialisation efforts. ■

#### Cardio Renal Conference: Physicians Link Patient Care

osprey's sales initiatives encompass strong regional activities, for which the recent Cardio Renal Connections Conference provided an opportune venue highlighting the benefits of DyeVert. Sponsored by the University of Texas (San Antonio) Divisions of Cardiology and Nephrology, this conference focused on the interplay of Chronic Kidney and Cardiovascular Diseases.

Providing a forum for both academic and private-practice professionals in cardiology and nephrology, the conference addressed the close relationship of renal function and cardiac function, giving rise to the concept of *cardio-renal syndromes*. Blending with Osprey technologies, specific topics included Contrast-Induced Acute Kidney Injury prevention and risk factors such as hypertension and diabetes.

With the epidemic of diabetes and the aging population in the United States, physicians will continue to face a growing number of patients with renal and cardiovascular disease.



## DyeVert Pilot Results Highlighted at EuroPCR

On May 19, 2016 in Paris, France, results of the DyeVert Pilot Trial were presented at the European Association of Percutaneous Cardiovascular Intervention's annual conference (EuroPCR). EuroPCR is one of the world's largest international conferences in the area of cardiovascular medicine with over 12,000 attendees

Professor Steffen Desch presented outcomes of the 44-patient study, which was performed at the Heart Centre in Lübeck, Germany, and Monash Medical Centre in Melbourne, Australia. Monash's Dr. James Sapontis was the principal investigator of the study. This prospective, single arm pilot trial found that the DyeVert System saved 47.4% contrast dye on average in all patients — 50.3% in PCI/Stenting and 46.6% in diagnostic procedures.

As expected, the study found DyeVert's dye savings benefit did not affect image quality.

Physicians reported that even though DyeVert reduced the amount of contrast dye dose delivered to the patient by nearly half, the X-ray visualisation was maintained. They also noted that the system was easy to use.

Professor Desch commented, "The results of this trial are very promising for patients suffering from poor kidney function. We now have an easy-to-use, self-adjusting, next-generation device that significantly reduces the amount of contrast volume delivered to the patient without compromising image quality. This allows us to protect the kidneys of those patients that are at highest risk of further damage."

The DyeVert System, Osprey's second-generation product, has received both European CE Mark and US FDA Clearance. This system is currently in US commercialisation and is the key offering to accelerate market adoption.

Study groups	Attempted (Average mLs)	Delivered to Patient (Average mLs)	Saved (Average mLs)	% Saved (Average)
All (N=44 patients)	172.9	88.7	84.1	47.4%
PCI/Stenting (N=10)	343.8	168.3	175.5	50.3%
Diagnostic (N=34)	122.6	65.3	57.3	46.6%



## Osprey in the Media

## Herald Sun Surgery device boon for Osprey

# THE AGE Osprey to market efficiency of DyeVert





Interview with Osprey Medical CEO Mike McCormick

http://www.finnewsnetwork.com.au/archives/finance news network123301.html

#### FORWARD LOOKING STATEMENTS

This document contains certain forward-looking statements, relating to Osprey Medical's business, which can be identified by the use of forward-looking terminology such as "promising," "plans," "anticipated," "will," "project," "believe," "forecast," "expected," "estimated," "targeting," "aiming," "set to," "potential," "seeking to," "goal," "could provide," "intends," "is being developed," "could be," "on track," or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA's and other health authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any health authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialization of the product candidates could be affected by, among other things, unexpected clinical trial results, including additional analysis of existing clinical data, and new clinical data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property.

#### AVERT<sup>™</sup> and DyeVert<sup>™</sup> Systems Regulatory Status:

- Europe CE Mark obtained
- Australia TGA approval obtained
- United States 510(k) cleared

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