

**Analyst**

John Hester 612 8224 2871

**Authorisation**

Tanushree Jain 612 8224 2849

# Osprey Medical (OSP)

## Dose Sales Accelerate

**Speculative**  
 Refer to key risks on page 4 and Biotechnology Risk Warning on page 6. Speculative securities may not be suitable for retail clients.

**Recommendation**

**Buy** (unchanged)

**Price**

**\$0.25**

**Valuation**

**\$0.53** (previously \$0.52)

**Risk**

**Speculative**

**GICS Sector**

**Healthcare Equipment and Services**

**Expected Return**

Capital growth	<b>112%</b>
Dividend yield	<b>0.0%</b>
Total expected return	<b>112%</b>

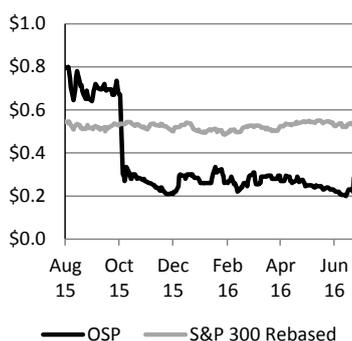
**Company Data & Ratios**

Enterprise value	<b>\$30.5m</b>
Market cap	<b>\$38.5m</b>
Issued capital	<b>154.2m</b>
Free float	<b>100%</b>
Avg. daily val. (52wk)	<b>\$63,000</b>
12 month price range	<b>\$0.19 - \$0.85</b>

**Price Performance**

	(1m)	(3m)	(12m)
Price (A\$)	0.23	0.30	0.63
Absolute (%)	23.91	-3.39	-54.76
Rel market (%)	25.56	-8.06	-49.58

**Absolute Price**



**June quarter dose sales grew strongly**

Osprey Medical has today reported 45% sequential quarter unit sales growth for 2Q16. Average Selling Price was maintained at US\$355 per unit. This is in line with our revenue expectation and follows 53% growth in the 1Q16. We estimate the company sold 540 units in 1H16 relative to our full year forecast of 1,800 unit sales.

Osprey piloted its commercialisation efforts in San Antonio, Texas starting in early 2015. This territory passed an important milestone last month when it achieved profitability for the first time by exceeding the breakeven point of 75 units. The single sales rep in the territory achieved 100 unit sales across the 15 hospitals. Unit sales have continued to grow in each quarter and based on the run rate achieved in June together with the ongoing growth, we remain confident the company will meet the revenue forecast for 2016.

Earlier in the quarter Osprey released important subgroup analysis from the AVERT clinical trial which appears to have contributed to the unit sales growth achieved this quarter. The sub group analysis showed up to a 49.5% reduction in the occurrence of contrast induced nephropathy (CIN) in patients with stage 3 kidney disease.

For hospitals and physicians at risk of penalty for above average rates of CIN events the evidence from this large randomised clinical trial is compelling. The results from the sub group where presented at a major interventional cardiology conference in May 2016 and this coincided with the expansion of the sales force to 8 territories.

For these two key reasons we expect a rapid expansion in the number of samples provided to new hospitals during 3Q16. The conversion rate of hospitals upgrading from samples to initial product orders is approximately 85%.

**Maintain Buy Rating, Valuation Raised to \$0.53**

There are no changes to earnings. DCF valuation is raised from \$0.52 to \$0.53. We maintain our Buy rating.

**Earnings Forecast**

December Year End US\$m	FY15	FY16e	FY17e	FY18e
Revenues	0.2	0.6	4.2	13.3
EBITDA \$m	-12.2	-10.6	-10.4	-6.1
NPAT (underlying) \$m	-12.2	-10.2	-10.0	-5.7
NPAT (reported) \$m	-12.2	-10.2	-10.0	-5.7
EPS underlying (cps)	-8.3	-4.3	-4.2	-2.4
EPS growth %	19%	-49%	-2%	-43%
PER (x)	-3.0	-5.8	-5.9	-10.5
FCF yield (%)	-30%	-17%	-18%	-10%
EV/EBITDA (x)	-2.5	-2.9	-2.9	-5.0
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	0.0%	-49.9%	-91.7%	-107.5%

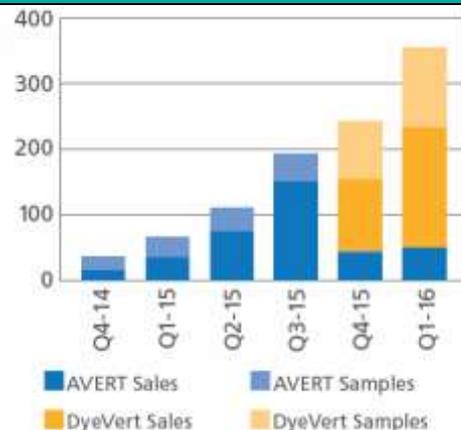
SOURCE: IRESS

SOURCE: BELL POTTER SECURITIES ESTIMATES

# Still Early Days For Revenue Growth

The company has recently provided the following analysis of unit sales:

**Figure 1 - Units sales data**



SOURCE: COMPANY DATA

Based on this chart and some assumptions around today’s update, we estimate Osprey had generated 540 unit sales in the six months ended 30 June 2016. The expanded sales force of 8 (current) and growing to 20 by year end should comfortably see the company meet our target of 1,800 unit sales by calendar year end.

### NEXT CATALYSTS

- The company is trialling a next generation DyeVert System. The release data has not yet been announced, however could reasonably be expected to be later this year.
- The Society for Cardiovascular Angiography and Interventions (SCAI) recently updated Guidelines for best practice in the cardiac catheterisation lab to heighten focus on:
  1. Real time monitoring of contrast use, using as little contrast as possible; and
  2. Cath lab staff must inform physicians when predetermined limits are reached (based on patient work up prior to procedure).

The DyeVert System is the only system indicated to meet these requirements. We expect the next generation of DyeVert will include enhanced monitoring and recording features that will further enhance benefits to hospital and patients.

We expect the expanded sales force to continue to drive traction in the market based on the following clinical evidence recently presented at major interventional cardiology conferences.

**Figure 2 - Post hoc analysis of CIN using serum creatinine change >0.5mg/dl**

Study Group	Patient numbers	Mean Reduction in CIN
		for AVERT vs control group
All patients	470	20.5%
Diagnostic (angiography)	268	28.5%
PCI/Stenting	202	13.6%
<b>Patients with stage 3 kidney disease</b>	<b>264</b>	<b>49.5%</b>

SOURCE: COMPANY DATA

Across all patients, the Avert group experienced a 20.5% reduction in CIN events. In patients with moderate stage chronic kidney disease, there were 264 patients across the

control group and AVERT group. The mean reduction in CIN events was 49.5% in the AVERT group vs the control group (p=.02).

The sub group analysis also included the following evidence concerning dye savings:

**Figure 3 - Initial sub group analysis - AVERT v control**

	<b>Dye Savings</b>
Angiogram only - no further intervention	<b>8%</b>
All PCI	<b>23%</b>
PCI - 1 blockage	<b>15%</b>
PCI - 2 blockages	<b>31%</b>
PCI - 3 or more blockages	<b>46%</b>

SOURCE: BELL POTTER SECURITIES ESTIMATES

The analysis shows that in the most serious cases involving more than one cardiac arterial blockage, the dye savings were far greater than where no intervention was required (i.e. angiogram only). **In cases involving 3 or more blockages, the dye saving when using Avert was 46% compared to the control group.**

# About Osprey Medical

Osprey Medical is a US based company focused on the development and commercialisation of its proprietary DyeVert System. DyeVert aims to reduce the level of contrast used in certain diagnostic procedures involving the heart. Contrast Induced Nephropathy (CIN) is a serious medical condition related to kidney failure and is a side effect following use of contrast (dye) in angioplasty/cardiac stenting procedures.

Approximately 25% of patients undergoing angioplasty or cardiac stenting are at high risk of a CIN event due to their pre-existing kidney disease.

It is estimated there are up to 1.6m procedures (amongst high risk patients) conducted in the US each year that may benefit from the use of this technology. The DyeVert system has multiple measures aimed at minimising the volume of dye used, which should help reduce the number of CIN events in at risk patients.

Extensive clinical trials have now been completed in Australia, Europe and the US resulting in regulatory approvals in each of these jurisdictions.

In the US Osprey has its own dedicated sales force and does not use distributors and neither does the sales force sell any other products. It commenced marketing of the predecessor to DyeVert in 2014 with a single sales rep in Texas. Since then, it has recorded seven consecutive quarters of growth in units sold and sampled. We expect this trend will continue as the company intends to expand the number of sales reps over the remainder of 2016 from the current seven to twenty. In addition the company has added clinical specialists to assist the interventional cardiologist and nursing staff in their initial use of the system and training as required.

The conversion rate of hospitals upgrading from DyeVert samples to initial product orders remains high at approximately 85%. As the volume of samples expands, it is logical to assume commercial orders will follow.

There are four key drivers for physicians and hospitals to adopt the technology:

- Clinical trials proved there is up to 46% reduction in dye usage when the system is used as compared to when not used. The saving is highest in patients requiring multiple stents. Key opinion leaders in the US consistently advocate using less dye in order to reduce the risk of CIN events;
- Sub group analysis from the Avert trial showed a 49.5% reduction in the rate of CIN events in patients with grade 3 chronic kidney disease;
- Patients suffering a CIN event normally require additional hospitalisation for up to four days at a cost of up to \$10K per day to hospitals with little or no incremental payer reimbursement; and
- Medicare/Medicaid payments to hospitals are at risk if the rate of unplanned readmission for Medicare patients exceeds the national average. Targeted re-admission includes heart failure and heart attack. Any patient admitted with chest pain is likely to meet this criteria. The penalties are severe and include a 3% revenue penalty on ALL Medicare payments to the effected hospital.

The company has invested approximately US\$50m in the development of the technology to this point where it is now approved in major markets and generating revenues in the US. The company expects to commence a roll out in Europe in 2017. We expect the company will become breakeven by FY19 when revenues are expected to exceed US\$20m.



**Recommendation structure**

**Buy:** Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

**Hold:** Expect total return between -5% and 15% on a 12 month view

**Sell:** Expect <-5% total return on a 12 month view

*Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.*

*Such investments may carry an exceptionally high level of capital risk and volatility of returns.*

**Research Team**

Staff Member	Title/Sector	Phone	@bellpotter.com.au
TS Lim	Head of Research	612 8224 2810	tslim
<b>Industrials</b>			
Sam Haddad	Industrials	612 8224 2819	shaddad
John O'Shea	Industrials	613 9235 1633	joshea
Chris Savage	Industrials	612 8224 2835	csavage
Jonathan Snape	Industrials	613 9235 1601	jsnape
Sam Byrnes	Industrials	612 8224 2886	sbyrnes
John Hester	Healthcare	612 8224 2871	jhester
Tanushree Jain	Healthcare/Biotech	612 8224 2849	tnjain
<b>Financials</b>			
TS Lim	Banks/Regionals	612 8224 2810	tslim
Lafitani Sotiriou	Diversified	613 9235 1668	Isotiriou
<b>Resources</b>			
David Coates	Resources	613 9235 1833	showe
Peter Arden	Resources	613 9235 1731	parden
<b>Associates</b>			
Tim Piper	Associate Analyst	612 8224 2825	tpiper
Hamish Murray	Associate Analyst	61 3 9256 8761	hmurray

**Bell Potter Securities Limited**

ACN 25 006 390 7721

Level 38, Aurora Place  
88 Phillip Street, Sydney 2000

Telephone +61 2 9255 7200

www.bellpotter.com.au

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