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Speculative

Refer to key risks on page 4 and Biotechnology Risk Warning on page 7. Speculative securities may not be suitable for retail clients.

## Osprey Medical

### Sales Force Gaining Traction

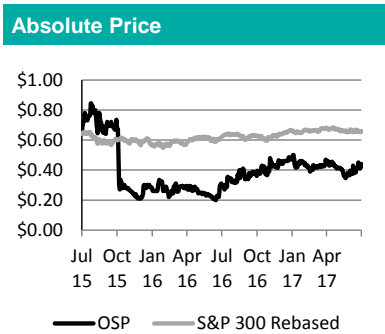
**Recommendation**  
**Hold** (Buy)  
**Price**  
**\$0.45**  
**Valuation**  
**\$0.53** (previously \$0.55)  
**Risk**  
**Speculative**

**GICS Sector**  
**Healthcare Equipment and Services**

Expected Return	
Capital growth	<b>17.8%</b>
Dividend yield	<b>0%</b>
Total expected return	<b>17.8%</b>

Company Data & Ratios	
Enterprise value	<b>\$98m</b>
Market cap	<b>\$116m</b>
Issued capital	<b>257.9m</b>
Free float	<b>100%</b>
Avg. daily val. (52wk)	<b>\$81,000</b>
12 month price range	<b>\$0.255 - \$0.51</b>

Price Performance			
	(1m)	(3m)	(12m)
Price (A\$)	0.38	0.43	0.30
Absolute (%)	15.79	3.53	49.15
Rel market (%)	14.74	5.69	39.79



SOURCE: IRESS

### All Territories Continuing To Build

The Osprey 2Q17 update contained pleasing news for unit sales and revenues growth, however, we have downgraded our full year revenue forecast based on this result. Importantly the downgrade to earnings represents a slower than anticipated uptake in unit sales rather than a downgrade to the overall market size. FY17 and FY18 earnings are impacted, however we continue to believe the company will achieve breakeven in FY19.

The highlights of the 2Q17 result were the 42% quarter on quarter unit sales growth while maintaining average selling price of ~US\$355. Unit sales growth in the two established sales territories of San Antonio and Atlanta continued at approximately 15% (sequential). Also pleasing was the traction now evident in the 16 more recently established territories where average monthly unit sales per sales rep more than doubled, albeit still well short of breakeven.

On a company wide basis, total sales for 1H17 were 1,961 units (US\$698K). We now expect 2H17 sales of ~4,500 units (US\$1.6m).

Cash receipts for 1H17 were US\$584K (83% of revenues). Cash expenses for the half were approximately US\$7.0m which is modestly higher than forecast. At the end of the quarter cash reserves were US\$15.1m.

For FY17 the forecast NPAT loss is increased by US\$2.0m to US\$12.9m while in FY18, the forecast NPAT loss increases from US\$4.5m to US\$7.3m. There are no material changes to earnings for FY19.

Recommendation is reduced from Buy to Hold following recent share price movement. Valuation is amended to \$0.53 from \$0.55 following earnings changes.

We have made no allowance at this time for revenues from the recently announced DyeTect product due for full release in late calendar 2017. The product is highly complimentary to existing sales of Dyvert Plus and will be marketed by the same sales team. Future sales represent upside to our forecast revenues and earnings.

Earnings Forecast				
December Year End US\$m	FY16	FY17e	FY18e	FY19e
Revenues	0.6	2.3	10.6	29.8
EBITDA \$m	-11.6	-13.0	-7.7	4.7
NPAT (underlying) \$m	-11.7	-12.9	-7.3	5.1
NPAT (reported) \$m	-11.7	-12.9	-7.3	5.1
EPS underlying (cps)	-6.2	-5.0	-2.8	2.0
EPS growth %	-26%	20%	43%	na
PER (x)	-7.3	-9.0	-15.8	22.8
FCF yield (%)	-9%	-12%	-7%	3%
EV/EBITDA (x)	-7.9	-7.1	-11.9	19.6
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	-54.2%	-149.1%	-557.7%	70.6%

SOURCE: BELL POTTER SECURITIES ESTIMATES

# Momentum Building

We highlight the key statistics from the quarterly report as follows:

**Figure 1 - Highlights from 2Q17**

	Q116	Q216	Q316	Q416	1Q17	2Q17	1H17	2H17e
Total Unit sales	245	334	446	636	812	1,149	1,961	4,500
Revenues (US\$'000)	87	119	156	223	290	408	698	1,598
Purchasing hospitals	27	29	39	45	55	75		
<b>Average unit sale per rep/month</b>								
San Antonio	43	60	65	79	105	121		
Atlanta	6	28	39	47	78	91		
All other territories	na	na	3	5	5	11		

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

Total units sales for 1H17 were 1,961 relative to our forecast of 2,200. Revenues for the period were US\$698K relative to the forecast of US\$800K. On both measure the actuals were approximately 12% below forecast.

There were a number of highlights in the 2Q17 result.

- San Antonio continued to gather momentum increasing sequential quarter unit sales by 15%;
- Atlanta increased sequential quarter unit sales by 16%;
- Average monthly unit sales per sales rep in all other territories more than doubled (from 5 to 11). It is worthwhile to note that most of these 16 staff were hired in 2H16. We estimate an average length of time in the field of about 8 months; and
- The number of purchasing hospital increased by 36% in the quarter and the number of samples provided increased by 15%.

Each of these signals points towards continued strong growth in revenues for 2H17. All aspects of the result were pleasing despite the shortfall on our forecast.

The company will continue to expand its sales force with the addition of approximately 10 new reps in various new territories across the US commencing from now. We do not expect these will have any material impact on revenues until 1H18.

Notwithstanding this impressive growth, our prior full year estimate for the year ended December 2017 was for unit sales of 12,000. This implied approximately 10,000 unit sales in 2H17 and it appears unachievable. Nevertheless it is a delay in our short term forecast, not the long term outlook. We now expect the company will increase 2H17 unit sales by 129% over the first half to ~4,500 units (down from 10,000).

Our adjusted earnings profile is as follows.

**Figure 2 - Earnings Changes**

	2017			2018			2019		
	Old	New	% Change	Old	New	% Change	Old	New	% Change
Device sales	12,000	6,461	-46%	39,000	30,240	-22%	84,000	85,800	2%
US\$m									
Revenues	4.2	2.3	-45%	13.3	10.6	-20%	27.2	29.8	10%
EBITDA	-11.0	-13.0	-18%	-4.9	-7.7	-58%	4.2	4.7	12%
NPAT	-10.9	-12.9	-18%	-4.5	-7.3	-63%	4.6	5.1	11%
EPS	-4.2	-5.0	-19%	-1.7	-2.8	-68%	1.8	2.0	10%

SOURCE: BELL POTTER SECURITIES ESTIMATES

The key adjustments in FY17 and FY18 are the reductions to unit sales volumes and the addition of approximately \$500K in sales staff cost in FY17. There are no significant changes to the cost base for FY18 as we had previously allowed for this headcount expansion.

**The sales force required to achieve the long term revenue projection is now in place**

We have also amended the forecast in relation to the roll out for Europe, previously estimated to commence in FY18. The company now intends to achieve breakeven in the US prior to pursuing a roll out in Europe. Osprey now expects to become cash flow breakeven in late CY2019 which effectively delays the European roll out until 2020.

The net impact to revenues for the group is minimal as the enlarged US sales force of ~28 is higher than we had anticipated. The incremental revenue generation should compensate for the delayed European roll out.

In terms of this strategy change, delaying the roll out in Europe is sensible in our view. Pricing and margins in the US are likely to be significantly higher than Europe. Europe also requires a distributor model, hence is likely to be lower margin.

We have made no allowance at this time for revenues from the recently announced DyeTect product due for full release in late calendar 2017. DyeTect is designed to monitor (but not minimise) contrast usage in non-chronic kidney disease patients undergoing cardiac intervention involving use of contrast dye. The product is highly complimentary to existing sales of Dyvert Plus and will be marketed by the existing sales team. The product has been developed in response to market demand amongst existing hospital clients, hence strong reason to believe that a portion these clients will support the product.

The guidelines for adoption of DyeTect are not as compelling as they are for DyVert. Ideally contrast use should be kept to a minimum for all patients, however, patients with normal renal function have a very low risk of AKI (~5%). Nevertheless, at US\$149 the device is cheap to use.

The company estimates the annual revenue potential (of DyeTect across US & Europe) at \$525m (assuming full market penetration). In our view revenue of US\$0.5 - \$2m in the first year (2018) are reasonable (bearing in mind it will be for the US market only).

# Key Risk Areas

The clinical trial(s) which led to the approval of the first generation AVERT system and subsequent additions are now completed. Although these trials were ultimately not able to prove a reduction in CIN events, the claims for use of the product remain strong.

## **Market Adoption Risk**

To achieve the sales revenue objectives, patients, physicians, hospitals and payers must accept the company's products, specifically the DyeVert™ system, for routine use. Regulatory approvals of the company's products, including US FDA approval, does not guarantee market adoption. Acceptance of the company's products in Europe and the US will be dependent on numerous factors, including but not necessarily limited to, market perception of the risk of CIN, risk benefit and cost-benefit analysis of the use of the company's products and reimbursement.

## **Technical Risk**

The reasons for CIN are not fully understood by the medical community and are potentially multi-factorial and variable for each patient based on their health history and disease state. Given this patient variability there is no guarantee that minimising the amount of dye used will reduce the incidence of CIN.

## **Intellectual Property Risk**

The company relies on its ability to obtain and maintain patent protection of products such as the DyeVert™ System. The company's patent portfolio comprises 8 issued US patents, 15 pending US patents, and 10 international patents. There are also National Stage Applications in the EU, Japan and Australia.

## **Manufacturing and Product Quality Risk**

Osprey' products must also meet the regulatory requirements which are subject to continual review including inspections by regulatory authorities including the US FDA. Failure by the company or its suppliers to continuously comply with applicable regulatory requirements or failure to take satisfactory corrective action in response to adverse inspection, could result in enforcement actions, including a public warning letter, a shutdown of, or restrictions on, its manufacturing operations, delays in approving or clearing products, refusal to permit the import or export of its products or other enforcement action.

# 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 consistently grown units sold and sampled. We expect this trend will continue as the company intends to expand the number of sales reps. 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 2018. We expect the company will become breakeven by FY19 when revenues are expected to exceed US\$20m.

Table 1 - Financial summary

Profit & Loss (US\$m)	FY15	FY16	FY17e	FY18e	FY19e
<b>Year Ending December</b>					
Device unit sales	430	1,661	6,461	30,240	85,800
Net revenue from product sales	0.2	0.6	2.3	10.6	29.8
<b>COGS</b>	<b>-0.4</b>	<b>-0.7</b>	<b>-1.1</b>	<b>-2.6</b>	<b>-6.4</b>
<b>Gross profit</b>	<b>-0.2</b>	<b>0.3</b>	<b>1.1</b>	<b>8.0</b>	<b>23.4</b>
<b>GP margin</b>	<b>0%</b>	<b>50%</b>	<b>50%</b>	<b>76%</b>	<b>79%</b>
R&D incentive/Upfront receipts	-	-	-	-	-
<b>Total revenues</b>	<b>0.2</b>	<b>0.6</b>	<b>2.3</b>	<b>10.6</b>	<b>29.8</b>
<b>Other expenses</b>					
<b>EBITDA</b>	<b>-12.0</b>	<b>-11.4</b>	<b>-14.1</b>	<b>-15.8</b>	<b>-18.8</b>
<b>D&amp;A</b>	<b>-12.2</b>	<b>-11.6</b>	<b>-13.0</b>	<b>-7.7</b>	<b>4.7</b>
<b>D&amp;A</b>	<b>0.0</b>	<b>-0.1</b>	<b>-0.1</b>	<b>-0.1</b>	<b>-0.1</b>
<b>EBIT</b>	<b>-12.2</b>	<b>-11.7</b>	<b>-13.1</b>	<b>-7.8</b>	<b>4.6</b>
Sundry income	0.1	0.0	0.2	0.5	0.5
Pre tax profit	-12.2	-11.7	-12.9	-7.3	5.1
Tax expense	-	-	-	-	-
<b>NPAT - normalised</b>	<b>-12.2</b>	<b>-11.7</b>	<b>-12.9</b>	<b>-7.3</b>	<b>5.1</b>
Net abnormal items	-	-	-	-	-
<b>Reported NPAT</b>	<b>-12.2</b>	<b>-11.7</b>	<b>-12.9</b>	<b>-7.3</b>	<b>5.1</b>
<b>Cashflow (US\$m)</b>					
Gross cashflow	-11.6	-10.5	-13.9	-8.5	3.4
Net interest	0.3	0.0	0.2	0.5	0.6
Tax paid	0.0	0.0	0.0	0.0	0.0
<b>Operating cash flow</b>	<b>-11.4</b>	<b>-10.5</b>	<b>-13.7</b>	<b>-8.0</b>	<b>4.0</b>
Maintenance capex	-0.1	-0.4	-0.2	-0.2	-0.2
Capitalised clinical trial spend	0.0	0.0	0.0	0.0	0.0
<b>Free cash flow</b>	<b>-11.5</b>	<b>-10.9</b>	<b>-13.9</b>	<b>-8.2</b>	<b>3.8</b>
Business acquisitions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	11.9	21.0	0.0	0.0	0.0
Movement in investments	0.0	0.0	0.0	0.0	0.0
Dividends paid	0.0	0.0	0.0	0.0	0.0
<b>Change in cash held</b>	<b>0.4</b>	<b>10.1</b>	<b>(13.9)</b>	<b>(8.2)</b>	<b>3.8</b>
Cash at beginning of period	11.3	11.8	21.8	7.9	(0.3)
<b>Cash at year end</b>	<b>11.8</b>	<b>21.8</b>	<b>7.9</b>	<b>(0.3)</b>	<b>3.5</b>
<b>Balance Sheet (US\$m)</b>					
Cash	11.8	21.8	7.9	(0.3)	3.5
Receivables	-	0.1	0.5	2.4	6.9
Short term investments	0.3	0.3	0.3	0.3	0.3
Other current assets	0.1	-	-	-	-
Property, Plant and Equipment	0.3	0.5	0.6	0.7	0.8
Intangible assets	0.1	0.1	0.1	0.1	0.1
<b>Total assets</b>	<b>12.6</b>	<b>22.8</b>	<b>9.5</b>	<b>3.3</b>	<b>11.6</b>
Trade payables /accruals	1.0	1.1	0.6	1.8	5.0
Other liabilities	-	-	-	-	-
Debt - interest bearing debt	-	0.1	0.1	0.1	0.1
<b>Total Liabilities</b>	<b>1.0</b>	<b>1.2</b>	<b>0.7</b>	<b>1.9</b>	<b>5.1</b>
<b>Net Assets</b>	<b>11.6</b>	<b>21.6</b>	<b>8.8</b>	<b>1.4</b>	<b>6.5</b>
Share capital	64.8	86.5	86.5	86.5	86.5
Retained earnings	(53.2)	(64.9)	(77.8)	(85.1)	(80.0)
Reserves	-	-	-	-	-
<b>Shareholders Equity</b>	<b>11.6</b>	<b>21.6</b>	<b>8.8</b>	<b>1.4</b>	<b>6.5</b>

Valuation Ratios (US\$m)	FY15	FY16	FY17e	FY18e	FY19e
Reported EPS (cps)	-8.3	-6.2	-5.0	-2.8	2.0
Normalised EPS (cps)	-8.3	-6.2	-5.0	-2.8	2.0
EPS growth (%)	19%	-26%	20%	43%	na
<b>PE(x)</b>	<b>-5.4</b>	<b>-7.3</b>	<b>-9.0</b>	<b>-15.8</b>	<b>22.8</b>
<b>EV/EBITDA (x)</b>	<b>-7.5</b>	<b>-7.9</b>	<b>-7.1</b>	<b>-11.9</b>	<b>19.6</b>
<b>EV/EBIT (x)</b>	<b>-7.5</b>	<b>-7.9</b>	<b>-7.1</b>	<b>-11.7</b>	<b>20.1</b>
NTA (cps)	7.4	8.3	3.3	0.5	2.5
P/NTA (x)	6.1	5.4	13.4	90.2	18.2
Book Value (cps)	7.5	8.4	3.4	0.5	2.5
Price/Book (x)	6.0	5.4	13.3	82.5	17.9
DPS (cps)	-	-	-	-	-
Payout ratio %	0%	0%	0%	0%	0%
Dividend Yield %	0.0%	0.0%	0.0%	0.0%	0.0%
Franking %	170%	0%	0%	0%	0%
FCF yield %	-17%	-9%	-12%	-7%	3%
Net debt/Equity	0%	0%	0%	21%	0%
Net debt/Assets	0%	0%	0%	8%	0%
Gearing	0%	net cash	net cash	17%	net cash
Net debt/EBITDA (x)	n/a	n/a	n/a	n/a	n/a
Interest cover (x)	n/a	n/a	n/a	n/a	n/a

Unit sales	FY16	FY17e	FY18e	FY19e
Europe	-	-	-	1,800
USA	1,661	6,461	30,240	84,000
Australia/Asia Pacific	-	-	-	-
<b>Total unit sales</b>	<b>1,661</b>	<b>6,461</b>	<b>30,240</b>	<b>85,800</b>
Average revenue per sale US\$'000	352	350	350	347

Half Year Earnings Split	1H16	2H16	1H17e	2H17e
Unit sales	590	1,071	1,961	4,500
Revenues	0.2	0.4	0.7	1.6
EBIT	-6.1	-5.6	-5.7	-7.4
NPAT	-6.1	-5.6	-5.6	-7.3

SOURCE: BELL POTTER SECURITIES ESTIMATES

**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.*

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**Biotechnology Risk Warning:**

The stocks of biotechnology companies without revenue streams from product sales or ongoing service revenue should always be regarded as speculative in character. Since most biotechnology companies fit this description, the speculative designation also applies to the entire sector. The fact that the intellectual property base of a typical biotechnology company lies in science and not generally regarded as accessible to the layman adds further to the riskiness with which biotechnology investments ought to be regarded. Stocks with 'Speculative' designation are prone to high volatility in share price movements. Clinical and regulatory risks are inherent in biotechnology stocks. Biotechnology developers usually seek US FDA approval for their technology which is a long and arduous three phase process to prove the safety, effectiveness and appropriate application or use of the developed drug, and even after approval a drug can be the subject of an FDA investigation of subsequently discovered possible links between the drug and other un-previously diagnosed diseases. Investors are advised to be cognisant of these risks before buying such a stock including **Osprey Medical** (of which a list of specific risks is highlighted within).

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