BELL POTTER

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Osprey (OSP)

Speculative
Refer to key risks on page 3 and Biotechnology Risk Warning on page 6.

European Pilot Sites To Commence In 2017

Recommendation
Buy (unchanged)
Price
$0.415
Valuation
$0.55 (unchanged)
Risk
Speculative

GICS Sector

Healthcare Equipment and Services

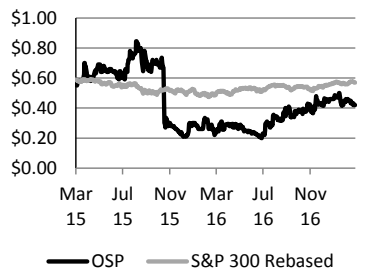
Expected Return	
Capital growth	**32.5%**
Dividend yield	**0.0%**
Total expected return	**32.5%**

Company Data & Ratios	
Enterprise value	**$79.3m**
Market cap	**$107.1m**
Issued capital	**257.8m**
Free float	**100%**
Avg. daily val. (52wk)	**$63,000**
12 month price range	**$0.195 - $0.51**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.44	0.43	0.26
Absolute (%)	-4.55	-1.18	61.54
Rel market (%)	-5.85	-6.87	46.58

Absolute Price



SOURCE: IRESS

FY16 EBITDA Loss In Line

OSP reported its full year result for calendar 2016 today. It achieved revenues of $585K and a loss at the EBITDA line of $11.6m. Revenues had been previously announced and the EBITDA result was close to the forecast.

OSP continues to aggressively roll out the Dyvert system in the US with the number of new sales territories set to expand further in 2017. In addition to the 13 sales reps hired in late 2016, the company now has plans to extend this to 28 in 2017. If the company reaches this target, the volume of sales reps will exceed our forecast by 8 heads. As there is an extended period of ramp up for each rep, earnings in 2017 are heavily skewed to the backend of the year.

We see two short term catalysts for unit sales growth. At last count there were 45 hospital buyers with a pipeline of 40 hospitals in the evaluation stage. We expect a majority of the pipeline hospitals to convert to commercial customers in 1Q17. As the volume of hospital using the device grows each quarter, we anticipate a high probability that volumes should grow in line. In 4Q16 the 16 hospitals in the pilot district of San Antonio Texas each acquired 15 units on average.

Secondly, the imminent launch of Dyevert Plus in the US should further improve utilisation rates. The key advantage of Dyevert Plus is the real time monitoring of usage of contrast and for physicians to be informed when the pre-planned limit of contrast use has been reached.

Also in 2017 the company will initiate EU commercial pilot activities in several European countries ahead of full EU commercialisation planned for 2018.

OSP has US$21.8m of cash as at 31 December 2016.

Maintain Buy Rating And Valuation at $0.55

There are no significant changes to our earnings forecast and we maintain our buy rating.

Earnings Forecast

December Year End US$m	FY16	FY17e	FY18e	FY19e
Revenues	0.6	4.2	13.3	27.2
EBITDA $m	-11.6	-11.0	-4.9	4.2
NPAT (underlying) $m	-11.7	-10.9	-4.5	4.6
NPAT (reported) $m	-11.7	-10.9	-4.5	4.6
EPS underlying (cps)	-6.2	-4.2	-1.7	1.8
EPS growth %	-26%	32%	59%	na
PER (x)	-6.7	-9.8	-23.8	23.3
FCF yield (%)	-10%	-11%	-5%	3%
EV/EBITDA (x)	-7.2	-7.6	-16.9	19.8
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	-54.2%	-103.4%	-80.4%	37.9%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Sales Reps Continue to Expand

Figure 1 - 2016 Results Summary

	2015	2016		
	Actual	Actual	Forecast	% change
Unit sales	**494**	**1,661**	**1,661**	
Revenues US$'000	173.0	585.0	585.0	0.0%
EBITDA	-12.2	-11.6	-11.0	-5.1%
NPAT	-12.2	-11.7	-10.6	-9.3%
EPS (cps)	-8.3	-6.2	-5.6	-9.6%
Closing cash balance (31 Dec 2016)		21,800		
Last qtr's annualised cash burn rate		10,800		

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

For FY17 the loss at EBITDA was $600K higher than anticipated. The majority of this differential may be attributed to a US$158K loss at the gross line. This is a volume related item and we anticipate that gross profit will turn positive at approximately 360 units per month.

Summary Financial Results – 4Q16

The key points from the 4Q16 cash flow statement and sales commentary were as follows:

- Units sales growth of 43% vs 3Q16. The company sold 636 DyeVert units in the quarter relative to 446 in prior quarter. 2H16 unit sales grew by 86%.
- We continue to expect exponential revenue growth in FY17 driven by the expanded sales force now in place. Excluding the pilot sales territory of San Antonio, units sales in other 14 territories were 400 units in total or an average of 28 units per territory for the quarter. This equates to less than 10 units per month per territory.
- Conversely, the single sales rep in the San Antonio sold 236 units or the quarter or 79 units per month.

Our forecast for FY17 stands at 12,000 units which we derive from a bottom up methodology. The key assumptions are:

- An average of 20 reps in the field across the US. We understand the company will have up to 20 reps by the end of 1Q17 with plans to expand to 28 reps by the end of 2017.

OSP achieved 1,661 unit sales for the year.

- Closing cash was US$21.8m. The net cash burn for the quarter was US$2.7m.

Figure 2 - Summary of earnings changes

	2017			2018			2019		
	Old	New		Old	New		Old	New	
Unit sales	**12,000**	**12,000**	**% change**	**39,000**	**39,000**	**% change**	**84,000**	**84,000**	**% change**
US$m									
Revenues	4.2	4.2	0.0%	13.3	13.3	-0.2%	27.2	27.2	-0.1%
EBITDA	-10.3	-11.0	-6.7%	-4.9	-4.9	0.0%	4.2	4.2	0.0%
NPAT	-9.9	-10.9	-10.0%	-4.5	-4.5	0.0%	4.6	4.6	0.0%
EPS	-3.9	-4.2	-8.3%	-1.7	-1.7	-2.7%	1.8	1.8	-0.9%

SOURCE: BELL POTTER SECURITIES

We anticipate the next data point will be the announcement of FDA approval of the Dyevert Plus before 31 March, followed by the March quarter sales which should be announced to the market in late April.

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.

Osprey
as at 27 February 2017

Recommendation	Buy, Speculative
Price	$0.415
Valuation	$0.55

Table 1 - Financial summary

Profit & Loss (US$m)	FY15	FY16	FY17e	FY18e	FY19e
Year Ending December					
Device unit sales	430	1,661	12,000	39,000	84,000
Net revenue from product sales	0.2	0.6	4.2	13.3	27.2
COGS	-0.4	-0.7	-2.1	-3.2	-5.8
Gross profit	-0.2	0.3	2.1	10.1	21.4
GP margin	0%	50%	50%	76%	79%
R&D incentive/Upfront receipts	-	-	-	-	-
Total revenues	**0.2**	**0.6**	**4.2**	**13.3**	**27.2**
Other expenses	**-12.0**	**-11.4**	**-13.1**	**-15.0**	**-17.2**
EBITDA	**-12.2**	**-11.6**	**-11.0**	**-4.9**	**4.2**
D&A	0.0	-0.1	-0.1	-0.1	-0.1
EBIT	-12.2	-11.7	-11.1	-5.0	4.1
Sundry income	0.1	0.0	0.2	0.5	0.5
Pre tax profit	-12.2	-11.7	-10.9	-4.5	4.6
Tax expense	-	-	-	-	-
NPAT- normalised	-12.2	-11.7	-10.9	-4.5	4.6
Net abnormal items	-	-	-	-	-
Reported NPAT	-12.2	-11.7	-10.9	-4.5	4.6

Cashflow (US$m)	FY15	FY16	FY17e	FY18e	FY19e
Gross cashflow	-11.6	-10.5	-11.9	-5.8	3.3
Net interest	0.3	0.0	0.2	0.5	0.5
Tax paid	0.0	0.0	0.0	0.0	0.0
Operating cash flow	-11.4	-10.5	-11.7	-5.3	3.8
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
Free cash flow	-11.5	-10.9	-11.9	-5.5	3.6
Business acquistions	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
Change in cash held	0.4	10.1	(11.9)	(5.5)	3.6
Cash at beginning of period	11.3	11.8	21.8	9.9	4.3
Cash at year end	11.8	21.8	9.9	4.3	7.9

Balance Sheet (US$m)					
Cash	11.8	21.8	9.9	4.3	7.9
Receivables	-	0.1	1.0	3.1	6.3
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
Total assets	12.6	22.8	11.9	8.6	15.5
Trade payables /accruals	1.0	1.1	1.1	2.2	4.5
Other liabilities	-	-	-	-	-
Debt - interest bearing debt	-	0.1	0.1	0.1	0.1
Total Liabilities	1.0	1.2	1.2	2.3	4.7
Net Assets	11.6	21.6	10.7	6.2	10.8
Share capital	64.8	86.5	86.5	86.5	86.5
Retained earnings	(53.2)	(64.9)	(75.8)	(80.3)	(75.7)
Reserves	-	-	-	-	-
Shareholders Equity	11.6	21.6	10.7	6.2	10.8

Valuation Ratios (US$m)	FY15	FY16	FY17e	FY18e	FY19e
Reported EPS (cps)	-8.3	-6.2	-4.2	-1.7	1.8
Normalised EPS (cps)	-8.3	-6.2	-4.2	-1.7	1.8
EPS growth (%)	19%	-26%	32%	59%	na
PE(x)	**-5.0**	**-6.7**	**-9.8**	**-23.8**	**23.3**
EV/EBITDA (x)	-6.8	-7.2	-7.6	-16.9	19.8
EV/EBIT (x)	-6.8	-7.1	-7.5	-16.6	20.2
NTA (cps)	7.4	8.3	4.1	2.4	4.1
P/NTA (x)	5.6	5.0	10.1	17.5	10.0
Book Value (cps)	7.5	8.4	4.2	2.4	4.2
Price/Book (x)	5.5	5.0	10.0	17.2	9.9
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 %	-18%	-10%	-11%	-5%	3%
Net debt/Equity	0%	0%	0%	0%	0%
Net debt/Assets	0%	0%	0%	0%	0%
Gearing	0%	net cash	net cash	net cash	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	-	-	3,000	18,000
USA	1,661	12,000	36,000	66,000
Australia/Asia Pacific	-	-	-	-
Total unit sales	**1,661**	**12,000**	**39,000**	**84,000**
Average revenue per sale US$'000	352	350	340	323

Half Year Earnings Split	1H16	2H16	1H17e	2H17e
Unit sales	590	1,071	2,200	9,800
Revenues	0.2	0.4	0.8	3.4
EBIT	-6.1	-5.6	-6.1	-5.0
NPAT	-6.1	-5.6	-6.0	-4.9

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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