BELL POTTER

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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.

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Osprey Medical (OSP)

34% Units Sales Growth in 3Q16

Recommendation
Buy (unchanged)
Price
$0.385
Valuation
$0.53 (unchanged)
Risk
Speculative

GICS Sector

Healthcare Equipment and Services

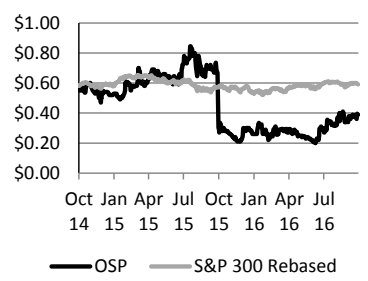
Expected Return	
Capital growth	**37.7%**
Dividend yield	**0.0%**
Total expected return	**37.7%**

Company Data & Ratios	
Enterprise value	**$66.7m**
Market cap	**$99.2m**
Issued capital	**257.7m**
Free float	**100%**
Avg. daily val. (52wk)	**$74,000**
12 month price range	**$0.19 - $0.67**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.35	0.31	0.70
Absolute (%)	13.04	25.81	-44.29
Rel market (%)	9.52	25.02	-48.30

Absolute Price



SOURCE: IRESS

Key Points from September Quarterly Update

The company achieved 34% unit sales growth across all territories for the quarter. Unit sales in the pilot sales territory of San Antonio continue to expand. There are now 8 additional territories under development and the cumulative unit sales of these now exceeds that of San Antonio.

San Antonio is on the cusp of its maiden quarter of profitability following two years of market development. Further, we understand some hospitals have indicated a reduction of up to 50% in the number of acute kidney injuries following adoption.

Sales momentum is continuing to accelerate. During the September quarter, the number of hospital buyers expanded by 33% to 39. There is a pipeline of 40 additional hospitals across the new sales territories currently evaluating the system.

Osprey continues to aggressively role out its expansion plans in the US and restated its commitment to have 20 sales reps in place by year end. Following the recent hire of 2 new reps, there are now 11 reps in total.

The commentary from the company indicates that in leading hospitals who were amongst the first adopters in San Antonio, DyeVert is now used in up to 90% of cases involving angiogram for high risk acute kidney injury patients. This penetration rate has grown from an initial 20% and has gradually increased as more interventional cardiologists begin to use DyeVert. The company estimates the broader adoption rate is approximately 40%, albeit there are no published statistics to support this claim.

Maintain Buy Rating, Valuation Remains $0.53

There are no significant changes to our earnings forecast. The DCF valuation is maintained at $0.53 and we maintain our Buy rating. The number of hospitals using DyeVert continues to expand each quarter and it is reasonable to expect this will continue to grow. We conclude that the execution of the sales plan continues to progress well.

Earnings Forecast

December Year End US$m	FY15	FY16e	FY17e	FY18e
Revenues	0.2	0.6	4.2	13.3
EBITDA $m	-12.2	-11.0	-10.3	-4.9
NPAT (underlying) $m	-12.2	-10.6	-9.9	-4.5
NPAT (reported) $m	-12.2	-10.6	-9.9	-4.5
EPS underlying (cps)	-8.3	-4.9	-3.9	-1.7
EPS growth %	19%	-42%	-20%	-55%
PER (x)	-4.6	-7.9	-10.0	-22.1
FCF yield (%)	-19%	-11%	-11%	-5%
EV/EBITDA (x)	-6.1	-6.8	-7.3	-15.4
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	0.0%	-50.4%	-86.7%	-66.0%

SOURCE: BELL POTTER SECURITIES ESTIMATES

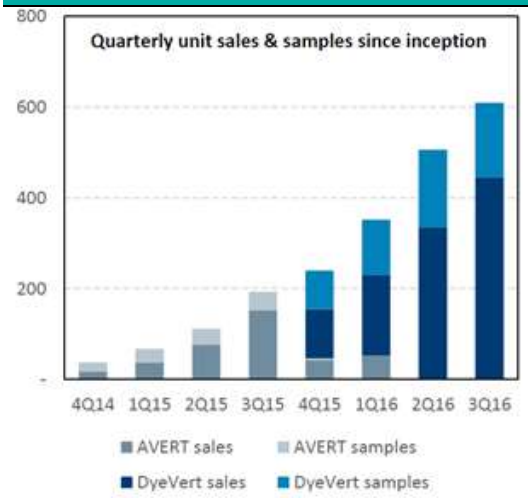
40 New Hospitals Evaluating DyeVert

Summary Financial Results – 3Q16

The key points from the 3Q16 cash flow statement and sales commentary were as follows:

- Units sales growth of 34% vs 2Q16. The company sold 446 DyeVert units in the quarter relative to 334 in prior quarter and approximately 579 for the entire 1H16.
- In the pilot sales territory in San Antonio, Texas unit sales continued to accelerate quarter on quarter at 9%. The company exceeded its breakeven target of 75 units per month in June 2016, however, for the September quarter units sales fell short of breakeven at 196 units. We expect the San Antonio sales territory will exceed the breakeven point for the December quarter.

Figure 1 - Quarterly Unit Sales and Samples



SOURCE: COMPANY DATA

Figure 2 - Average Selling Price History

	Q116	Q216	Q316
Unit sales	245	334	446
Revenues US$'000	87	119	156
Average selling price US$	**355**	**356**	**349**

SOURCE: COMPANY DATA

- 70% of hospitals in the San Antonio sales area have now approved the product for use and have bought the product. This result has been achieved in only two years. We expect the take up rate to accelerate in new territories because the product now has the support of robust clinical data – which only became available in May 2016.
- Ex – San Antonio, unit sales were 250 units for the quarter and significantly exceeded sales in the original pilot market. This result covers 8 sales territories. New territories added this quarter include San Francisco, St. Louis, Milwaukee, Chicago, Cincinnati and Philadelphia. The commonality between these cities is the large population and an abundance of hospitals in each city. Northern California for example has 250 hospitals.
- OSP has recently hired sales reps number 10 and 11. The company remains on target to have 20 sales territories by the end of the calendar year.
- Free samples are provided to new hospital trialling the product. The volume of samples issued in the quarter continues to be a strong proxy for the subsequent unit sales growth. 40 new hospitals (across all territories) are in the evaluation to purchase cycle.
- 39 hospitals acquired product in 3Q16 representing an increase of 33% over the prior sequential quarter.

With 79 new hospitals either evaluating or having recently commenced use of the product we continue to anticipate ongoing growth in the final quarter of 2016.

Our unit sales target for the calendar year is 1,800 units. We estimate OSP has sold more than 1,000 units so far this year, hence the full year target is a stretch. While our timing may be a little aggressive there is no doubt that the sales momentum is building on multiple fronts. We anticipate the release of actual hospital savings (either in dollars or the number of CIN events) may be a major catalyst for future sales.

- Operating expenses for the quarter were US$2.39m (2Q16: US$2.95m). Most of the reduction in expenses is attributable to a US$350K reduction in R&D expenditure. R&D expense had been elevated due to the development of the DyeVert Plus system in preceding months;
- We expect the run rate on staff costs will accelerate in the near term as the sales force expands to 20 by the end of the calendar year;
- Cash receipts from customers were US$123K as compared to US$113K in the prior sequential period;
- OSP raised net U$21m from the issue of new securities in the period; and
- Closing cash was US$24.4m.

We expect that at 75 units per sales rep per month by 12 months from hire, the annualised rate of sales by December 2017 will be approximately 18,000 units or revenues of US$6.4m.

DYEVERT PLUS

DyeVert Plus is the latest release product from the company. Its key value add is real time monitoring against a pre-set limit for dye use. The product has received approval in the US and was recently submitted to the FDA for approval as supplementary approval. The FDA is expected to grant approval within 90 days of submission.

Valuation and Recommendation

As there are no significant changes to earnings forecasts, we retain the valuation of $0.53 and the Buy recommendation. We had previously allowed for the dilution from the capital raise that was completed in July 2016.

The valuation continues to be based on a Discounted Cash Flow model.

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 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. 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.

Osprey Medical
as at 17 October 2016

Recommendation	Buy, Speculative
Price	$0.385
Valuation	$0.53

Table 1 - Financial summary

Profit & Loss (US$m)	FY15	FY16e	FY17e	FY18e	FY19e
Year Ending December					
Device unit sales	430.0	1,800	12,000	39,000	84,000
Net revenue from product sales	0.2	0.6	4.2	13.3	27.2
COGS	-0.4	-0.3	-0.8	-2.7	-5.4
Gross profit	-0.2	0.3	3.4	10.6	21.7
GP margin	0%	50%	80%	80%	80%
R&D incentive/Upfront receipts	-	-	-	-	-
Total revenues	**0.2**	**0.6**	**4.2**	**13.3**	**27.2**
Other expenses	**-12.0**	**-11.3**	**-13.7**	**-15.5**	**-17.6**
EBITDA	**-12.2**	**-11.0**	**-10.3**	**-4.9**	**4.2**
D&A	0.0	-0.1	-0.1	-0.1	-0.1
EBIT	-12.2	-11.1	-10.4	-5.0	4.1
Sundry income	0.1	0.5	0.5	0.5	0.5
Pre tax profit	-12.2	-10.6	-9.9	-4.5	4.6
Tax expense	-	-	-	-	-
NPAT- normalised	-12.2	-10.6	-9.9	-4.5	4.6
Net abnormal items	-	-	-	-	-
Reported NPAT	-12.2	-10.6	-9.9	-4.5	4.6

Cashflow (US$m)	FY15	FY16e	FY17e	FY18e	FY19e
Gross cashflow	-11.6	-11.0	-10.8	-4.9	4.7
Net interest	0.3	0.5	0.5	0.5	0.5
Tax paid	0.0	0.0	0.0	0.0	0.0
Operating cash flow	-11.4	-10.5	-10.3	-4.4	5.2
Maintenance capex	-0.1	-0.2	-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	-10.7	-10.5	-4.6	5.0
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	10.3	(10.5)	(4.6)	5.0
Cash at beginning of period	11.3	11.8	22.0	11.6	7.0
Cash at year end	11.8	22.0	11.6	7.0	12.0

Balance Sheet (US$m)					
Cash	11.8	22.0	11.6	7.0	12.0
Receivables	-	0.1	0.5	1.7	3.4
Short term investments	0.3	0.3	0.3	0.3	0.4
Other current assets	0.1	0.1	0.1	0.1	0.1
Property, Plant and Equipment	0.3	0.4	0.5	0.6	0.7
Intangible assets	0.1	0.1	0.1	0.1	0.1
Total assets	12.6	23.0	13.1	9.8	16.7
Trade payables /accruals	1.0	1.0	1.1	2.2	4.5
Other liabilities	-	-	-	-	-
Debt - interest bearing debt	-	-	-	-	-
Total Liabilities	1.0	1.0	1.1	2.2	4.5
Net Assets	11.6	22.0	12.0	7.6	12.1
Share capital	64.8	85.8	85.8	85.8	85.8
Retained earnings	(53.2)	(63.8)	(73.8)	(78.2)	(73.7)
Reserves	-	-	-	-	-
Shareholders Equity	11.6	22.0	12.0	7.6	12.1

Valuation Ratios (US$m)	FY15	FY16e	FY17e	FY18e	FY19e
Reported EPS (cps)	-8.3	-4.9	-3.9	-1.7	1.8
Normalised EPS (cps)	-8.3	-4.9	-3.9	-1.7	1.8
EPS growth (%)	19%	-42%	-20%	-55%	na
PE(x)	**-4.6**	**-7.9**	**-10.0**	**-22.1**	**21.6**
EV/EBITDA (x)	-6.1	-6.8	-7.3	-15.4	18.0
EV/EBIT (x)	-6.1	-6.8	-7.2	-15.1	18.4
NTA (cps)	7.4	8.5	4.6	2.9	4.7
P/NTA (x)	5.2	4.5	8.3	13.3	8.2
Book Value (cps)	7.5	8.6	4.7	2.9	4.7
Price/Book (x)	5.1	4.5	8.2	13.1	8.2
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 %	-19%	-11%	-11%	-5%	5%
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	FY16e	FY17e	FY18e	FY19e
Europe	-	-	3,000	18,000
USA	1,800	12,000	36,000	66,000
Australia/Asia Pacific	-	-	-	-
Total unit sales	**1,800**	**12,000**	**39,000**	**84,000**
Average revenue per sale A$'000	-	350	340	323

Half Year Earnings Split	1H16	2H16e
Unit sales	590	1,210
Revenues	0.2	0.4
EBIT	-6.1	-5.0
NPAT	-6.1	-4.5

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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