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Osprey Medical (OSP)

New Sales Territories Underperform

Speculative
See key risks on Page 4 and Biotechnology Risk Warning on Page 7. Speculative securities may not be suitable for Retail Clients.

Recommendation
Hold (unchanged)
Price
$0.345
Valuation
$0.37 (previously $0.43)

GICS Sector

Healthcare Equipment and Services

Expected Return	
Capital growth	**7.2%**
Dividend yield	**0.0%**
Total expected return	**7.2%**

Company Data & Ratios	
Enterprise value	**$77.1m**
Market cap	**$117.1m**
Issued capital	**339.5m**
Free float	**100%**
Avg. daily val. (52wk)	**$82,000**
12 month price range	**$0.315 - $0.51**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.40	0.40	0.44
Absolute (%)	-5.00	-3.80	-13.18
Rel market (%)	-4.79	-6.42	-20.41

4Q17 Revenues Underwhelming

Osprey has now reported its 4Q17 cash flow and sales figures. Sales in the September quarter had been impacted by seasonal weather, therefore, the expectation was for a strong bounce in the December quarter. Osprey achieved DyeVert units sales of 1,376 units which represents 11% growth over the prior sequential quarter. This was below our expectation (of approximately 2,000 units) and judging from most of the questions on the investor call, investors were underwhelmed with the result. The net cash burn for the quarter was US$3.8m. Closing cash at 31 December was US$32.1m. Following this result we conclude that despite promising signs in most of the forward looking sales indicators, actuals sales in most jurisdictions have lagged well behind the trajectory established in San Antonio and Atlanta.

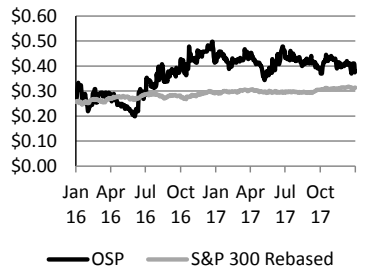
Fortunately the sales trends are not uniform across all territories. Two of the more recently established territories in North Carolina and Dallas, Texas have tracked more closely to the pilot in San Antonio. Both these territories are expected to shortly pass the breakeven point of 225 units per quarter.

In our view the major driver of the variability in hospital demand for DyeVert is probably cost. In other words, we have little doubt regarding the virtues of the product for patient safety, however, the unrelenting focus on measurement of all aspects of service delivery by US hospitals including cost per patient surgery must, at least in part, explain the slowness of the overall adoption rate for DyeVert. These factors have caused further downward adjustment to sales forecasts for FY18 and FY19.

Maintain Hold, Valuation amended to $0.37

Valuation is amended to $0.37 from $0.43 due to a rationalisation of revenue forecasts. It is now apparent that the majority of newer sales territories lag the pilot territory of San Antonio and subsequently the discounted cash flow valuation is amended accordingly. There are no material changes to FY17 earnings. The loss at EBITDA is increased by 41% to $11.0m in FY18. In FY19 we now expect an EBITDA loss of $11.5m. We retain our Hold recommendation.

Absolute Price



SOURCE: IRESS

Earnings Forecast

December Year End US$m	FY16	FY17e	FY18e	FY19e
Revenues	0.6	1.6	3.5	6.4
EBITDA $m	-11.6	-13.9	-11.0	-11.5
NPAT (underlying) $m	-11.7	-14.0	-11.1	-11.6
NPAT (reported) $m	-11.7	-14.0	-11.1	-11.6
EPS underlying (cps)	-6.2	-4.3	-3.3	-3.4
EPS growth %	-26%	30%	24%	na
PER (x)	-5.6	-8.0	-10.5	-10.1
FCF yield (%)	-12%	-13%	-10%	-10%
EV/EBITDA (x)	-6.7	-5.5	-7.0	-6.7
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	-54.2%	-42.6%	-51.0%	-113.8%

SOURCE: BELL POTTER SECURITIES ESTIMATES

4Q17 Performance Indicators

We summarise the KPI's for 4Q17 as follows:

Figure 1 - Q417 KPI's

	1Q16	2Q16	3Q16	4Q16	1Q17	2Q17	3Q17	4Q17
Total Unit sales	245	334	446	636	812	1,149	1,241	1,376
Sequential qtr growth	-	36%	34%	43%	28%	42%	8%	11%
Revenues (US$'000)	87	119	156	223	290	408	441	492
Purchasing hospitals	27	29	39	45	55	75	83	98
Hospitals in evaluation to purchase	-	-	-	40	39	46	52	62
Cash burn US$m	(2.9)	(2.8)	(2.3)	(2.5)	(3.6)	(3.1)	(3.3)	(3.8)
Bell Potter estimates								
Estimated Qty sales - San Antonio	128	180	196	236	314	363	320	400
Estimated Qty sales - Atlanta	17	84	117	140	235	272	200	300
Estimated Qty sales - All other territories					16	32	45	42

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

OSP achieved total DyeVert/ DyeVert Plus units sales of 4,578 units in FY17 vs 1,661 in the FY16.

We note the following key points from the December quarter results:

The two most important looking forward indicators have been a) purchasing hospitals and b) hospitals in evaluation to purchase. Both metrics have continued to show pleasing increases period on period.

While numerous hospitals continue to evaluate the DyeVert technology and most convert to paying customers, the volume of starting orders and subsequent orders has been slower than anticipated based on the experience in both San Antonio and Atlanta.

There are currently 18 sales territories. Excluding San Antonio and Atlanta, we estimate that in the remaining 16 territories, the average unit sales per rep in the December quarter was ~42 units. The majority of these reps were in place for the entire 2017 year and the trend in sales is lagging both San Antonio and Atlanta. The majority of these reps are still well short of breakeven (i.e. 255 units/qtr) after 1 year.

By comparison, San Antonio and Atlanta were both achieving well above 100 units/qtr at the same point in development. The more than 2x differential in sales performance across territories is driving the major under performance against our previous sales forecast.

This analysis has not escaped the attention of management. Two of the underperforming sales reps (Orlando and Chicago) left the company in late 2017 and will shortly be replaced. Management remain hopeful that the majority (of reps) can reach breakeven inside of 2 years.

KEY BARRIERS TO INCREASING ADOPTION

San Antonio, Atlanta and at least two of the new territories in South Carolina and Texas have continued to do well with each of these meeting expectation.

Of the others sales territories, many hospitals have placed initial small orders, however adoption rates do not appear to have matched the more successful sales territories. The reason for that is likely to be cost. In isolation DyeVert represents an additional cost of $355 per high risk case. It seems apparent that many hospitals are yet to be convinced that the opportunity costs of the $355 will ultimately save the hospital dollars in the long term. As Osprey explains, the level of cost measurement is now at the extreme level with some hospital groups even measuring cost per surgery down to the individual surgeon. This level of cost control is previously unheard of and it is apparent that despite the

availability of the technology, many surgeons are electing not to use DyeVert to save on cost.

Fortunately there is wide difference in opinion and practice. In San Antonio the company estimates a penetration rate in the addressable market of >50%.

The key strategy to address the adoption rates in the growing list of buying hospitals (there are now 98 active hospital buyers) is further clinical evidence including long term health economics data. The first of a series of papers on these topics is due in late calendar 2018. In the interim there is no quick fix. It is apparent that the health economics data to emerge from clinical trials now underway will be crucial for long term adoption.

FURTHER ADJUSTMENTS TO SHORT TERM REVENUE FORECASTS

As the adoption rates for DyeVert have fallen consistently below the pilot territory of San Antonio we now adjust revenue forecasts for FY18 and FY19 to reflect more realistic projections based on the sales growth achieved in new territories. As a result of these changes, cash flow breakeven is pushed out to FY22 (from FY19).

The company now expects the net cash burn will not exceed US$1.5m/month from this point forward. This is inclusive of a planned 17 new hires in 2018 inclusive of 10 new sales reps. The company has US$32.1m in cash as at 31 December.

Figure 2 - Summary of earnings changes

	2017			2018			2019		
	Old	New	% Change	Old	New	% Change	Old	New	% Change
Device sales	4,578	4,578	0%	26,640	9,960	-63%	67,440	18,340	-73%
US$m									
Revenues	1.9	1.6	-14%	9.3	3.5	-63%	23.6	6.4	-73%
EBITDA	-14.1	-13.9	1%	-7.8	-11.0	-42%	2.0	-11.5	large
NPAT	-14.2	-14.0	1%	-7.9	-11.1	-41%	1.9	-11.6	large
EPS	-4.4	-4.3	2%	-2.3	-3.3	-43%	0.6	-3.4	large

SOURCE: BELL POTTER SECURITIES ESTIMATES

Our valuation is amended to $0.37 from $0.43 and we maintain our Hold recommendation.

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.

Osprey Medical
as at 29 January 2018

Recommendation	Hold
Price	$0.345
Valuation (12 months)	$0.37

Table 1 - Financial summary

Profit & Loss (US$m)	FY15	FY16e	FY17e	FY18e	FY19e
Year Ending December					
Device unit sales	430	1,661	4,578	9,960	18,340
Net revenue from product sales	0.2	0.6	1.6	3.5	6.4
COGS	-0.4	-0.7	-1.5	-1.4	-1.4
Gross profit	-0.2	0.3	0.1	2.1	5.0
GP margin	0%	50%	0%	60%	79%
R&D incentive/Upfront receipts	-	-	-	-	-
Total revenues	**0.2**	**0.6**	**1.6**	**3.5**	**6.4**
Other expenses	**-12.0**	**-11.4**	**-14.1**	**-13.1**	**-16.6**
EBITDA	**-12.2**	**-11.6**	**-13.9**	**-11.0**	**-11.5**
D&A	0.0	-0.1	-0.1	-0.1	-0.1
EBIT	-12.2	-11.7	-14.0	-11.1	-11.6
Sundry income	0.1	0.0	-	-	-
Pre tax profit	-12.2	-11.7	-14.0	-11.1	-11.6
Tax expense	-	-	-	-	-
NPAT- normalised	-12.2	-11.7	-14.0	-11.1	-11.6
Net abnormal items	-	-	-	-	-
Reported NPAT	-12.2	-11.7	-14.0	-11.1	-11.6

Cashflow (US$m)	FY15	FY16e	FY17e	FY18e	FY19e
Gross cashflow	-11.6	-10.5	-14.9	-11.3	-11.7
Net interest	0.3	0.0	0.0	0.0	0.0
Tax paid	0.0	0.0	0.0	0.0	0.0
Operating cash flow	-11.4	-10.5	-14.9	-11.3	-11.7
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	-15.1	-11.5	-11.9
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	11.9	21.0	25.4	0.0	0.0
Movement in investments	0.0	0.0	0.0	0.0	0.0
Increases in debt	0.0	0.0	0.0	0.0	0.0
Change in cash held	0.4	10.1	10.3	(11.5)	(11.9)
Cash at beginning of period	11.3	11.8	21.8	32.1	20.6
Cash at year end	11.8	21.8	32.1	20.6	8.7

Balance Sheet (US$m)					
Cash	11.8	21.8	32.1	20.6	8.7
Receivables	-	0.1	0.4	0.8	1.5
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	33.5	22.6	11.4
Trade payables /accruals	1.0	1.1	0.4	0.6	1.1
Other liabilities	-	-	-	-	-
Debt	-	-	-	-	-
Provisions	-	0.1	0.1	0.1	0.1
Total Liabilities	1.0	1.2	0.5	0.7	1.2
Net Assets	11.6	21.6	33.0	21.9	10.2
Share capital	64.8	86.5	112.0	112.0	112.0
Retained earnings	(53.2)	(64.9)	(79.0)	(90.1)	(101.7)
Reserves	-	-	-	-	-
Shareholders Equity	11.6	21.6	33.0	21.9	10.2

Valuation Ratios (US$m)	FY15	FY16e	FY17e	FY18e	FY19e
Reported EPS (cps)	-8.3	-6.2	-4.3	-3.3	-3.4
Normalised EPS (cps)	-8.3	-6.2	-4.3	-3.3	-3.4
EPS growth (%)	19%	-26%	30%	24%	na
PE(x)	**-4.1**	**-5.6**	**-8.0**	**-10.5**	**-10.1**
EV/EBITDA (x)	-6.3	-6.7	-5.5	-7.0	-6.7
EV/EBIT (x)	-6.3	-6.6	-5.5	-6.9	-6.6
NTA (cps)	7.4	8.3	9.7	6.4	3.0
P/NTA (x)	4.6	4.1	3.6	5.4	11.6
Book Value (cps)	7.5	8.4	9.7	6.4	3.0
Price/Book (x)	4.6	4.1	3.5	5.4	11.5
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 %	-22%	-12%	-13%	-10%	-10%
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	-	-	-	240
USA	1,661	4,578	9,960	18,100
Australia/Asia Pacific	-	-	-	-
Total unit sales	**1,661**	**4,578**	**9,960**	**18,340**
Average revenue per sale US$'000	352	356	350	348

Half Year Earnings Split	1H16	2H16	1H17	2H17	1H18
Unit sales	590	1,071	1,961	2,617	6,419
Revenues	0.2	0.4	0.7	0.9	2.2
EBIT	-6.1	-5.6	-6.7	-7.3	-4.1
NPAT	-6.1	-5.6	-6.7	-7.3	-4.1

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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