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Osprey Medical (OSP)

Three GPO's Sign On

Speculative
Refer to key risks on page 5 and Biotechnology Risk Warning on page 7. Speculative securities may not be suitable for retail clients.

Recommendation
Buy (Hold)
Price
$0.245
Valuation
$0.35 (previously $0.37)
Risk
Speculative

GICS Sector

Healthcare Equipment and Services

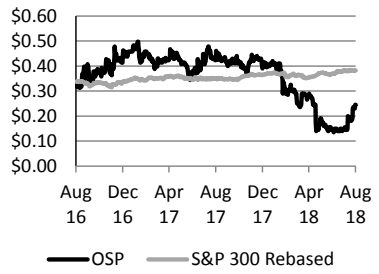
Expected Return	
Capital growth	**42.9%**
Dividend yield	**0.0%**
Total expected return	**42.9%**

Company Data & Ratios	
Enterprise value	**$52.5m**
Market cap	**$83.2m**
Issued capital	**339.5m**
Free float	**100%**
Avg. daily val. (52wk)	**$83,000**
12 month price range	**$0.135 - $0.46**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.15	0.15	0.43
Absolute (%)	68.97	68.97	-43.38
Rel market (%)	68.16	66.23	-52.81

Absolute Price



SOURCE: IRESS

Turning the corner

Osprey recently reported a pleasing result for 2Q18 with unit sales of Dyevert increasing by 25%. This result follows three quarters of lower than expected sales growth. In the leading sales territory of San Antonio unit sales grew by 25%. Across all other territories unit sales grew by 28%.

For the six months to June 2018 revenues were US$1.2m relative to operating costs of approximately $9.0m. Operating cash flow burn for the period was US$8.6m. As at 30 June 2018 Osprey had US$23.3m of cash. We expect cash burn is currently at its highest quarterly level and will gradually reduce as sales increase.

The key catalysts for the next year include the execution of three contracts with large Group Purchasing Organisations (GPO's) in the US with a further two signings likely this year. The three GPO's represent 250 hospitals of which just 15 (6%) are currently ordering Dyevert. The inclusion of Dyevert on the GPO buying lists represent a significant validation of the safety and value represented by the Dyevert system. On a practical basis, the GPO contracts should reduce the time for the hospital value analysis teams to complete their reviews and commence ordering.

A second catalyst will be the increasing frequency with which hospital clients are now demonstrating real world savings from the reduction of Acute Kidney Injury (AKI). Poster presentations at various conferences have shown that amongst high risk patient groups, AKI rates have been reduced by as much as 25%. These include a poster at the high profile Society for Cardiovascular Angiography and Interventions convention in May.

Upgrade to Buy

There are small changes to FY18 earnings, however, we believe the GPO contracts will be a key sales catalyst, hence FY19 sales projections are relatively unchanged. Valuation is reduced to $0.35 following dilution from an assumed capital raise in FY20. Despite these changes the upgrade to Buy is warranted based on the upside to our valuation.

Earnings Forecast

December Year End US$m	FY17	FY18e	FY19e	FY20e
Revenues	1.6	2.9	6.5	14.0
EBITDA $m	-13.9	-14.0	-12.7	-7.1
NPAT (underlying) $m	-14.0	-14.1	-12.9	-7.3
NPAT (reported) $m	-14.0	-14.1	-12.9	-7.3
EPS underlying (cps)	-4.3	-4.2	-3.8	-1.9
EPS growth %	30%	4%	na	50%
PER (x)	-0.1	-5.9	-6.5	-12.8
FCF yield (%)	-1814%	na	na	na
EV/EBITDA (x)	-3.8	-3.7	-4.1	-7.4
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	-42.6%	-74.8%	-212.9%	-66.5%

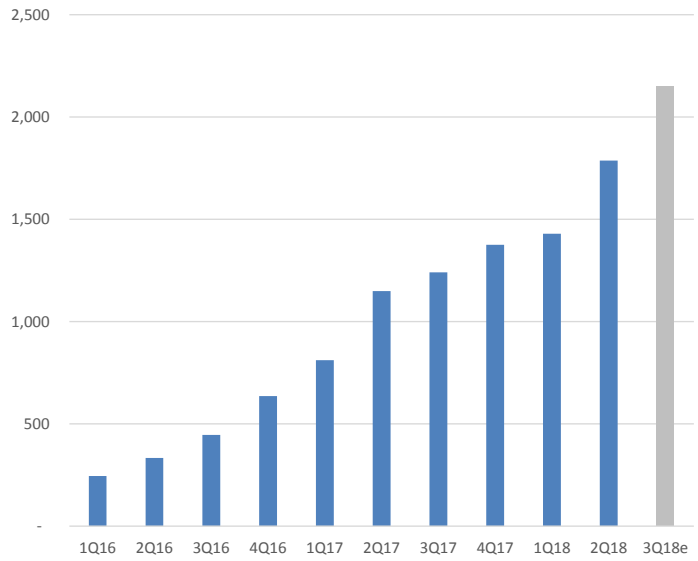
SOURCE: BELL POTTER SECURITIES ESTIMATES

2Q18 Sales Show Significant Growth

KEY POINTS FROM 2Q UPDATE

Easily the best quarter for Osprey for at least a year. Following mishaps with weather and revenue softness in key regions, the June quarter volumes increased by 25% quarter over quarter with the sales momentum continuing into the current quarter.

Figure 1 - Quarterly Dyvert Volumes



SOURCE: BELL POTTER SECURITIES

The company's experience over the last two and half years demonstrates just how challenging and expensive it is to commercialise new medical device technologies, particularly in the hands of a smaller company. While the market for such devices is appealing because of its scale, the hospital industry in the United States is geared for much larger corporations with significantly greater supply side presence.

The point is amply demonstrated with the signing in the June quarter of three separate national contracts with Group Purchasing Organisations (GPO's). Osprey did not identify which of the GPO's it has contracted, however, they are likely to come from the following list.

Figure 2 - GPO organisations in the US

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

As the name suggest, the GPO's offer value based agreements for their member hospitals. GPO's are not wholesalers. Their contracting teams guide hospital clients through the maze of products options evaluating clinical efficacy and overall cost of care to drive costs lower.

The input of the GPO has arguably never been more important than at the current moment as the US healthcare system moves away from fee for service to value based care. Purchasing decision to drive better clinical outcomes are now more important. Better clinical outcomes will keep patients out of hospital.

What is Value Based Care in Healthcare

The following quote is from Premier's hand book on Group Purchasing.

"Value analysis – a **systematic, objective process** for providing an **evidence based** methodology to evaluate current and **emerging technologies** in order to reduce/manage expenses by considering alternate products, services and practices which meet, but do not necessarily exceed, the clinical and end users specifications while **maintaining or improving safety and quality of patient care**."

Value analysis is all about standardisation of care processes (to the extent possible) and the elimination of waste, redundancy and inefficiency. It is far more than simply getting the best price, it is about the process. The Dyvert system for managing contrast use in PCI procedures is a part of a process that meets guideline requirements and now has the data to support broad based adoption.

The largest of the GPO's have thousands of member hospitals. Member hospitals are required to direct 80% of their procurement to products under contract with their GPO partners. Up to this point, Dyevert has not been a contracted product with any GPO, hence hospitals have automatically been hamstrung in the ordering the product because it has not been on a GPO product list with an ordering code.

Up to this point Osprey reps have had to approach individual hospital Value Analysis Teams (VAT) many of which follow the processes set by the GPO. Going outside of those protocols can be problematic and is certainly more time consuming. As these barriers begin to diminish Osprey expects the time from first sample through to first order will be reduced.

- There are a combined 250 member hospitals across the three contracted GPO's;
- The 18 Osprey sales reps cover 80% (200) of these hospitals;
- Currently 15 of 250 (6%) are users of the Dyvert System;
- The highest priorities for the Osprey sales force is to target the member hospitals of each GPO's and secondly to increase the penetration rate within each hospital.

Readers are reminded that guidelines for PCI consist of three key points:

- Screen for risk
- Increase hydration; and
- **Minimise contrast**

The following section addresses the company's ongoing efforts to demonstrate that Dyevert Plus is effective in reducing the volume of contrast used in high risk patients.

Society For Angiography And Interventions SCAI

The SCAI conference is the largest conference event in the US for interventional cardiology. Osprey sponsored a 114 patients study in high risk patients undergoing either a PCI or diagnostic coronary angiogram. This multicentre study, non-randomised study was designed to evaluate contrast media savings using Dyevert and evaluate the impact of pre-determined thresholds and real time monitoring. The data was collected from 9 participating hospitals.

The key points from the study were as follows:

- In this high risk patient group, the overall contrast media volume (CMV) saving was 40.1 ± 8.8% relative to the mean CMV attempted;
- The image quality was maintained in all but one case;
- The investigator concluded the data suggests the Dyevert Plus System used in subjects undergoing either procedure results in statistically significant and clinically meaningful CMV savings while maintaining image quality. AKI event rates increased as contrast volume to eGFR ratio increased[1].

These conclusions are entirely consistent with our understanding i.e. patients with poor kidney function (and therefore a low eGFR rate <60 mL/min) have a significantly higher risk of AKI. The risk increases as the contrast volume increases.

The data from this study is being prepared for a peer reviewed publication.

The abstract of this study was selected as one of the six best at the conference. Further studies of this nature are expected in the near term.

CASH FLOW

As at 30 June 2018 the company had cash of US$23.3m. Operating cash burn for the quarter was $4.3m. The company indicated its intention to hire additional sales force over the coming months, however, we anticipate the cash from additional sales should keep the cash burn consistent at the current level before beginning to decline.

Based on the latest projections, we have now included one further capital raise late 2020 before OSP turns cash flow positive.

The other key aspect of the cash flow data was manufacturing operating cost of $517K (for the 6 month period to 30 June). As the company carries virtually no inventory, this figure is likely to be a good proxy for COGS. The margin on sales is likely to be higher than the 30% we had anticipated and more towards 50%.

Figure 3 - Summary of earnings changes

	2018			2019		
	Old	New	% Change	Old	New	% Change
Device sales	9,960	7,885	-21%	18,340	18,580	1%
US$m						
Revenues	3.5	2.9	-18%	6.4	6.5	1%
EBITDA	-11.0	-14.0	-27%	-11.5	-12.7	-10%
NPAT	-11.1	-14.1	-27%	-11.6	-12.9	-11%
EPS	-3.3	-4.2	-26%	-3.4	-3.8	-12%

SOURCE: BELL POTTER SECURITIES ESTIMATES

The changes to forecast earnings incorporate our latest expectation for unit sales growth based on the June quarter sales and cash position. In spite of a downward adjustment to revenues in FY18 we believe the prospects for further share price appreciation are better now than at any time in the last year. The key driver of the change to recommendation is the signing of the GPO contracts.

The valuation is amended from $0.37 to $0.35 following the inclusion of an assumed capital raise in FY20. This may not be required if our forecasts are too conservative.

Figure 4 - Summary of key quarterly data

	1Q16	2Q16	3Q16	4Q16	1Q17	2Q17	3Q17	4Q17	1Q18	2Q18
Total Unit sales	245	334	446	636	812	1,149	1,241	1,376	1,430	1,787
Sequential qtr growth	0%	0%	0%	0%	28%	42%	8%	11%	4%	25%
Revenues (US$'000)	87	119	156	223	290	408	441	492	529	651
Purchasing hospitals	27	29	39	45	55	75	83	98	114	124
Hospitals in evaluation to purchase	-	-	-	40	39	46	52	62	45	28
Cash burn US$m	(2.9)	(2.8)	(2.3)	(2.5)	(3.6)	(3.1)	(3.3)	(3.8)	(4.4)	(4.2)

SOURCE: COMPANY DATA

[1] eGFR – estimated glomerular filtration rate, being a measure of how efficiently kidney's are functioning.

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 8 August 2018

Recommendation	Buy, Speculative
Price	$0.245
Valuation	$0.35

Table 1 - Financial summary

Profit & Loss (US$m)	FY16	FY17	FY18e	FY19e	FY20e
Year Ending December					
Device unit sales	1,661	4,578	7,885	18,580	38,760
Net revenue from product sales	0.6	1.6	2.9	6.5	14.0
COGS	-0.7	-1.5	-1.4	-2.6	-2.8
Gross profit	0.3	0.1	1.4	3.9	11.2
GP margin	50%	0%	50%	60%	80%
R&D incentive/Upfront receipts	-	-	-	-	-
Total revenues	**0.6**	**1.6**	**2.9**	**6.5**	**14.0**
Other expenses	**-11.4**	**-14.1**	**-15.5**	**-16.6**	**-18.3**
EBITDA	**-11.6**	**-13.9**	**-14.0**	**-12.7**	**-7.1**
D&A	-0.1	-0.1	-0.1	-0.1	-0.1
EBIT	-11.7	-14.0	-14.1	-12.8	-7.2
Interest expense	0.0	-	-	(0.1)	(0.1)
Pre tax profit	-11.7	-14.0	-14.1	-12.9	-7.3
Tax expense	-	-	-	-	-
NPAT- normalised	-11.7	-14.0	-14.1	-12.9	-7.3
Net abnormal items	-	-	-	-	-
Reported NPAT	-11.7	-14.0	-14.1	-12.9	-7.3

Cashflow (US$m)	FY16	FY17	FY18e	FY19e	FY20e
Gross cashflow	-10.5	-14.9	-14.2	-12.9	-7.5
Net interest	0.0	0.0	0.0	-0.1	-0.1
Tax paid	0.0	0.0	0.0	0.0	0.0
Operating cash flow	-10.5	-14.9	-14.2	-13.0	-7.6
Maintenance capex	-0.4	-0.2	-0.2	-0.5	-0.5
Capitalised clinical trial spend	0.0	0.0	0.0	0.0	0.0
Free cash flow	-10.9	-15.1	-14.4	-13.5	-8.1
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	21.0	25.4	0.0	0.0	12.0
Increase/(Decrease) in debt	0.0	0.0	0.0	0.0	0.0
Change in cash held	10.1	10.3	(14.4)	(13.5)	3.9
Cash at beginning of period	11.8	21.8	32.1	17.7	4.1
Cash at year end	21.8	32.1	17.7	4.1	8.0

Balance Sheet (US$m)					
Cash	21.8	32.1	17.7	4.2	8.0
Receivables	0.1	0.4	0.7	1.5	3.2
Short term investments	0.3	0.3	0.3	0.3	0.3
Other current assets	-	-	-	-	-
Property, Plant and Equipment	0.5	0.6	0.7	1.1	1.5
Intangible assets	0.1	0.1	0.1	0.1	0.1
Total assets	22.8	33.5	19.5	7.2	13.2
Trade payables /accruals	1.1	0.4	0.5	1.1	2.3
Other liabilities	-	-	-	-	-
Debt	-	-	-	-	-
Provisions	0.1	0.1	0.1	0.1	0.1
Total Liabilities	1.2	0.5	0.6	1.2	2.5
Net Assets	21.6	33.0	18.9	6.0	10.7
Share capital	86.5	112.0	112.0	112.0	124.0
Retained earnings	(64.9)	(79.0)	(93.1)	(106.0)	(113.2)
Reserves	-	-	-	-	-
Shareholders Equity	21.6	33.0	18.9	6.0	10.7

Valuation Ratios (US$m)	FY16	FY17	FY18e	FY19e	FY20e
Reported EPS (cps)	-6.2	-4.3	-4.2	-3.8	-1.9
Normalised EPS (cps)	-6.2	-4.3	-4.2	-3.8	-1.9
EPS growth (%)	-26%	30%	4%	na	50%
PE(x)	**0.0**	**-0.1**	**-5.9**	**-6.5**	**-12.8**
EV/EBITDA (x)	-4.5	-3.8	-3.7	-4.1	-7.4
EV/EBIT (x)	-4.5	-3.7	-3.7	-4.1	-7.3
NTA (cps)	8.3	9.7	5.5	1.7	2.8
P/NTA (x)	0.0	0.0	0.0	0.1	0.1
Book Value (cps)	8.4	9.7	5.6	1.8	2.8
Price/Book (x)	0.0	0.0	0.0	0.1	0.1
DPS (cps)	-	-	-	-	-
Payout ratio %	0%	0%	0%	0%	0%
Dividend Yield %	0.0%	0.0%	0.0%	0.0%	0.0%
Franking %	381%	0%	0%	0%	0%
FCF yield %	-1729%	-1814%	na	na	na
Net debt/Equity	0%	0%	94%	69%	75%
Net debt/Assets	0%	0%	973%	136%	154%
Gearing	net cash	net cash	48%	41%	43%
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	FY17	FY18e	FY19e	FY20e
Europe	-	-	240	1,800
USA	4,578	7,885	18,340	36,960
Australia/Asia Pacific	-	-	-	-
Total unit sales	**4,578**	**7,885**	**18,580**	**38,760**
Average revenue per sale US$'000	356	364	348	361

Half Year Earnings Split	2H16	1H17	2H17	1H18	2H18
Unit sales	1,071	1,961	2,617	3,217	4,668
Revenues	0.4	0.7	0.9	1.2	1.7
EBIT	-5.6	-6.7	-7.3	-7.9	-6.2
NPAT	-5.6	-6.7	-7.3	-7.9	-6.2

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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