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Osprey Medical (OSP)

Premier Contract Imminent

Speculative
Refer to key risks on page 5 and Biotechnology Risk Warning on page 8. Speculative securities may not be suitable for retail clients.

Recommendation
Buy (unchanged)
Price
$0.125
Valuation
$0.31 (previously $0.35)
Risk
Speculative

GICS Sector

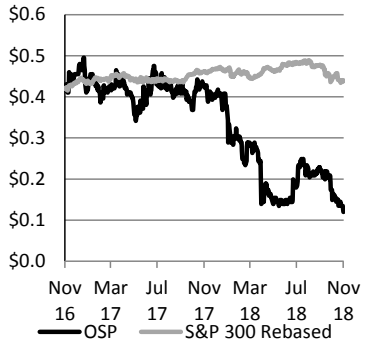
Healthcare Equipment and Services

Expected Return	
Capital growth	**148%**
Dividend yield	**0.0%**
Total expected return	**148%**
Company Data & Ratios	
Enterprise value	**$14.9m**
Market cap	**$58.9m**
Issued capital	**471m**
Free float	**100%**
Avg. daily val. (52wk)	**$69,000**
12 month price range	**$0.12 - $0.428**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.19	0.22	0.44
Absolute (%)	-38.1	-45.8	-72.6
Rel market (%)	-39.1	-37.4	-68.1

Absolute Price



SOURCE: IRESS

Turn around continues

Osprey recently reported 3Q18 unit sales growth of 3% (quarter over quarter). Relative to 3Q17, Dyevert units sales increased by 48%.

For the three months to September 2018 revenues were US$620K. Operating cash flow burn for the period was US$4.26m which is consistent with the burn rate for the first half of the year. As at 30 September 2018 Osprey had US$19.1m of cash.

Earlier this year the company executed three GPO contracts representing about 10% of the market for Dyevert. OSP is now on the cusp of a fourth GPO contract with Premier. Premier is the largest GPO in the US representing approximately 4,000 hospitals across dozens of hospital operators. On a cumulative basis across all four GPO contracts, Dyvert is now available to ~50% of its addressable market (i.e. high risk kidney patients) via GPO contracts.

The GPO value proposition is their ability to drive value based care. They focus member hospitals on standardised care pathways to improve patient outcomes and lower cost. An independent burden of illness study by Premier has clearly demonstrated the economic burden of acute kidney injury and this is likely to have been a key driver of the Breakthrough Technology Award for the Dyevert System.

In our view the announcement of these GPO contracts has been a significant catalyst for the $10m placement to Allan Grey together with a 1 for 5 rights issue to raise up to $10.5m ($20.5m in new capital in total).

Valuation Lowered, Maintain Buy (Speculative) Rating

There are no significant changes to earnings in the forecast period other than the dilution caused by the capital raise. FY19 is increasingly looking like the breakout year for Osprey Medical with the merits of the Dyevert system bound to get a better hearing from users over the course of the year. We had previously allowed for a capital raise in FY20. The announcement of the placement and rights issue is more dilution than we had previously allowed for, hence the valuation is reduced to by ~12% to $0.31.

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	-3.5	-2.7	-1.5
EPS growth %	30%	19%	22%	43%
PER (x)	0.0	-3.6	-4.6	-8.1
FCF yield (%)	-3556%	na	na	na
EV/EBITDA (x)	-1.1	-1.1	-1.2	-2.1
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	-42.6%	-35.8%	-48.2%	-37.4%

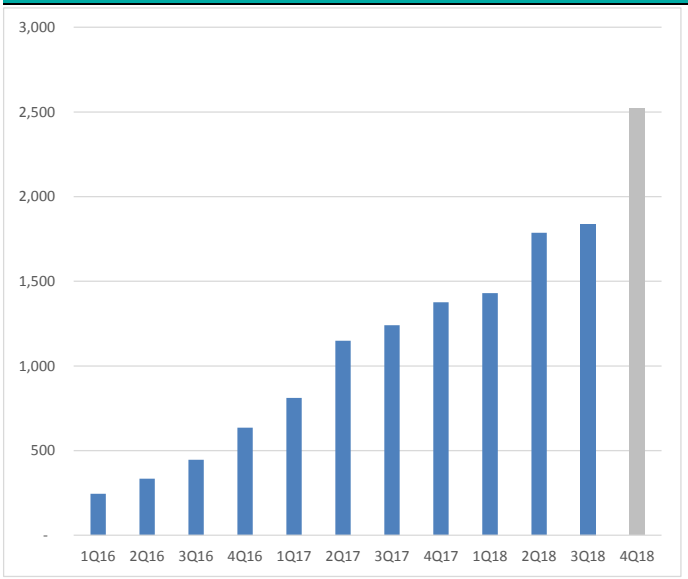
SOURCE: BELL POTTER SECURITIES ESTIMATES

Now achieving commercial validation

KEY POINTS FROM 3Q UPDATE

Dyvert unit volume sales increased by a modest 3% for the quarter following a 25% increase in the June quarter. The September quarter result includes some seasonality owing to the summer vacation period in the US. We expect a more significant increase in the December quarter as the holiday period has concluded and the GPO contracts begin to drive more significant volume growth.

Figure 1 - Quarterly Dyvert Volumes



SOURCE: BELL POTTER SECURITIES

GPO's (Group Purchasing Organisations) offer value based agreements for their member hospitals. GPO's are not wholesalers, rather their value proposition is to 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.

The largest GPO in the US is Premier which has ~4,000 member hospitals. Osprey expects enter into a contract with Premier in the December quarter. An agreement with Premier, together with the three signed GPO contracts, means that OSP will have access to hospitals via GPO contracts treating 50% of all cases of CKD (Chronic Kidney Disease) in the US (i.e. where those patients are candidates for Angiography).

PREMIER'S BURDEN OF ILLNESS STUDY

In its evaluation of the Dyevert technology (at least we assume it was connected), Premier conducted an analysis of charge code data for patients undergoing angiography procedures (being either heart imaging and or stenting) across 749 of its member hospitals. The key findings were as follows:

- The patient population in the study included those patients with chronic kidney disease (CKD) undergoing angiography;
- There were more than 2.8m cases over a 5 year period from 2012 to 2017;

- The mortality rate following the procedure was 61% higher in patients who had an acute kidney injury (AKI) vs those patients who did not have an AKI;

In our opinion, it stands to reason, that by reducing the rate of AKI, the post mortality death rate in this patient group should fall.

The data from this post hoc analysis is supported by real world data from St Mary's Medical Centre (a member of the Premier GPO) which reported a 25% reduction in AKI amongst its CKD population. The results of the (St Mary's) study will be published in a future medical journal. Neither the St Mary's study or the Burden Of Illness study were sponsored by Osprey, hence the credibility of the outcomes is enhanced.

Going back several years, we note that the pivotal study for the FDA approval of the original Avert technology did not meet the endpoint of a reducing the rate of AKI. There were multiple issue with the design of the pivotal trial study which contributed to this outcome.

We are not aware if the St Mary's study had a control, nevertheless, a 25% reduction in the rate of AKI in these high risk patients is prima facie evidence – from the real world setting, of a material benefit to patient outcomes. We note the following key points:

- By inference, it is reasonable to assume the hospital saved up to US$10K per day through not having to readmit patients as well as potentially avoiding Medicare revenue penalties that come with being in the bottom quartile of performance;
- The study did not quantify these savings, however published research shows that the contrast induced AKI patients are 15 times more likely to be hospitalised over 4 days, further, contrast induced AKI patients are 37% more likely to be re-admitted to hospital within a 30 day period. Normally the cost of the readmission within 30 days is borne by the hospital;
- Previous studies have shown an average dye saving of 40% in similar patient groups; and
- Probably as a result of this work, and following other evaluation by Premier, the DyeVert plus system received the Breakthrough Technology Award from Premier. This will allow Premier members to take advantage of special pricing and terms as negotiated by Premier for Osprey's technology.

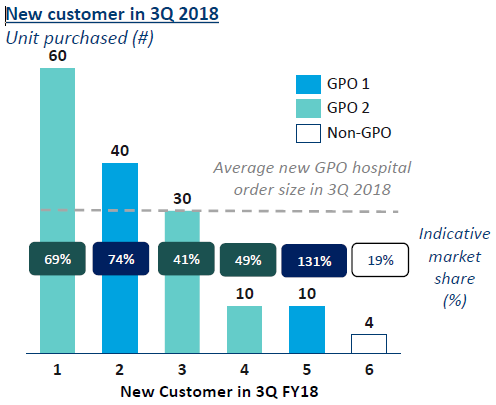
INCREASE IN AVERAGE ORDER SIZE FOR NEW GPO CUSTOMERS

We have previously noted the power of GPO relationships in reducing the time for the evaluation to purchase cycle. Contracting with GPO's can reduce this lead time from up to 6 months down to a few weeks. The GPO contract avoids the need for individual hospital procurement approvals. While individual hospitals are still likely the go through a period of product evaluation, the whole process is expedited by the relationship with the GPO.

In the following chart, each column represents a new hospital customer in 3Q18. The key points are:

- 5 of 6 new hospital clients in 3Q18 came from GPO relationships;
- In hospital 1, Dyvert was used in 69% of CKD patients. In other hospital clients (not on this chart) it has taken over 2 years to achieve this level of penetration;
- Average new order size in these new hospitals is 30 units. This compares to average sales per buying hospital of 14 units in 2Q18.

Figure 2 - New Customer Ordering 3Q18



SOURCE: COMPANY DATA

Following signing of the 3 GPO contracts, and the imminent signing of Premier, we continue to believe that over the course of the next rolling 12 months, units sales of the Dyevert system are likely to experience at least double digit quarter on quarter growth.

CAPITAL RAISING

The company agreed to a placement of $10m in new CDI's issue to the Sydney based fund manager Allan Grey. Allan Grey has a long and generally successful track record of investment in the healthcare sector. We note that it made a similar size investment in the ASX listed Nanosonics Limited (ASX:NAN) in the early stages of its commercialisation process in the US. We estimate Allen Grey will have a 14% stake in the company.

Existing shareholders have been offered the opportunity to avoid further dilution via a 1 for 5 entitlement offer with CDI's offered at the same price (15.5c) as the placement.

In total the company will issue 132 million new securities (off a base of 325 million at 31 December 2017). Following the new issuance and assuming a full take up of the rights issue the revised CDI on issue should be ~471 million.

We have previously allowed for an equity issuance in FY20. Following the adjustment for this capital raise (and assuming the rights offer is fully subscribed) our valuation is reduced to $0.31 (from $0.35).

Figure 3 - Summary of key quarterly data

	2018			2019			2020		
	New	Old	% Change	New	Old	% Change	New	Old	% Change
Device sales	7,885	7,885	0%	18,580	18,580	0%	38,760	38,760	0%
US$m									
Revenues	2.9	2.9	-1%	6.5	6.5	0%	14.0	14.0	0%
EBITDA	-14.0	-14.0	0%	-12.7	-12.7	0%	-7.1	-7.1	0%
NPAT	-14.1	-14	1%	-12.9	-12.9	0%	-7.3	-7.3	0%
EPS	-3.5	-4.2	-17%	-2.7	-3.8	-28%	-1.5	-1.9	-19%

SOURCE: COMPANY DATA

The only significant change to earnings is the dilution from the capital raise. Funds will be used primarily to expand the US sales team by an additional 4 to 6 heads and 5 to 8 new clinical specialists. These will focus on contracted GPO hospitals. Other uses of funds will be to provide additional working capital.

In essence, the company was not in the position that it needed this new capital, however, it is likely the offer from Allen Grey was unsolicited. We expect the board decided to accept the offer after consultation with major shareholders.

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.

Osprey Medical
as at 28 November 2018

Recommendation	Buy, Speculative
Price	$0.125
Valuation	$0.31

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	-7.6
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	-7.7
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	-8.2
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	21.0	25.4	20.5	0.0	0.0
Increase/(Decrease) in debt	0.0	0.0	0.0	0.0	0.0
Change in cash held	10.1	10.3	6.1	(13.5)	(8.2)
Cash at beginning of period	11.8	21.8	32.1	38.2	24.7
Cash at year end	21.8	32.1	38.2	24.7	16.5

Balance Sheet (US$m)					
Cash	21.8	32.1	38.2	24.7	16.5
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	22.9	33.5	40.0	27.7	21.7
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	39.4	26.5	19.2
Share capital	86.5	112.0	132.5	132.5	132.5
Retained earnings	(64.9)	(79.0)	(93.1)	(106.0)	(113.2)
Reserves	-	-	-	-	-
Shareholders Equity	21.6	33.0	39.4	26.5	19.2

Valuation Ratios (US$m)	FY16	FY17	FY18e	FY19e	FY20e
Reported EPS (cps)	-6.2	-4.3	-3.5	-2.7	-1.5
Normalised EPS (cps)	-6.2	-4.3	-3.5	-2.7	-1.5
EPS growth (%)	-26%	30%	19%	22%	43%
PE(x)	**0.0**	**0.0**	**-3.6**	**-4.6**	**-8.1**
EV/EBITDA (x)	-1.3	-1.1	-1.1	-1.2	-2.1
EV/EBIT (x)	-1.3	-1.1	-1.1	-1.2	-2.1
NTA (cps)	8.3	9.7	8.3	5.6	4.1
P/NTA (x)	0.0	0.0	0.0	0.0	0.0
Book Value (cps)	8.4	9.7	8.4	5.6	4.1
Price/Book (x)	0.0	0.0	0.0	0.0	0.0
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 %	-3388%	-3556%	na	na	na
Net debt/Equity	101%	97%	97%	93%	86%
Net debt/Assets	95%	96%	95%	89%	76%
Gearing	net cash	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	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	-8.9	-5.2
NPAT	-5.6	-6.7	-7.3	-8.8	-5.4

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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