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Osprey Medical (OSP)

Harvey and Irma Curtail Growth

Speculative
See key risks on Page 5 and Biotechnology Risk Warning on Page 8. Speculative securities may not be suitable for Retail Clients.

Recommendation
Hold (unchanged)
Price
$0.40
Valuation
$0.43 (previously $0.53)

GICS Sector

Healthcare Equipment and Services

Expected Return	
Capital growth	**7.5%**
Dividend yield	**0.0%**
Total expected return	**7.5%**

Company Data & Ratios	
Enterprise value	**$89.7m**
Market cap	**$135.7m**
Issued capital	**339.4m**
Free float	**100%**
Avg. daily val. (52wk)	**$75,000**
12 month price range	**$0.34 - $0.51**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.42	0.42	0.36
Absolute (%)	-4.76	-4.25	10.17
Rel market (%)	-7.34	-8.22	2.70

Q317 Revenues Modestly Disappointing

Q317 delivered mixed results for Osprey. The result was clearly influenced by the two category 4 hurricanes that had a catastrophic impact on the gulf coast including Osprey's leading sales territories. These storms were partly responsible for the overall modest 8% unit sales growth in the quarter.

On a brighter note, practically the entire market has now converted to Dyvert Plus from the Dyvert model. Clearly the market appreciates the real time monitoring of contrast usage that Dyvert Plus provides. The two key forward looking indicators of purchasing hospitals and hospitals in evaluation to purchase both grew during the period. Average selling price was sustained at $355/unit.

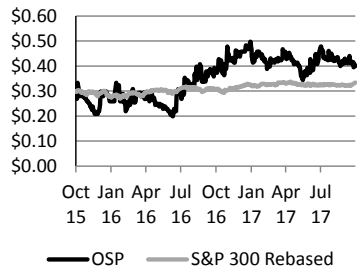
While the rate of acceleration of revenues growth is below our forecast, Osprey continues to make significant progress towards increasing market penetration. In the United States, there are now 83 hospital clients supported by 17 sales reps and 5 clinical specialists. We continue to believe this team together with the addition of 6 new reps or clinical specialists will support many quarters of double digit unit sales growth in the near future.

The net cash burn for the quarter was US$3.3m. Following the recent capital raise of US$25m, closing cash at 30 September 2017 was US$36m. The company issued approximately 81m new CDI's relating to the capital raise representing 32% of the previous volume of CDI's on issue.

FY17 revenues are downgraded by 18% while FY18 and FY19 revenues are downgraded by 12% and 20% respectively, however, we continue to forecast OSP will become breakeven in FY19.

Valuation is amended to $0.43 from $0.53 due to the combination of the dilution and earnings changes. We maintain our Hold recommendation. Osprey is yet to have its breakout quarter where multiple sales territories gain significant traction over a short period.

Absolute Price



SOURCE: IRESS

Earnings Forecast

December Year End US$m	FY16	FY17e	FY18e	FY19e
Revenues	0.6	1.9	9.3	23.6
EBITDA $m	-11.6	-14.1	-7.8	2.0
NPAT (underlying) $m	-11.7	-14.2	-7.9	1.9
NPAT (reported) $m	-11.7	-14.2	-7.9	1.9
EPS underlying (cps)	-6.2	-4.4	-2.3	0.6
EPS growth %	-26%	29%	47%	na
PER (x)	-6.5	-9.1	-17.3	71.9
FCF yield (%)	-11%	-11%	-6%	1%
EV/EBITDA (x)	-7.7	-6.4	-11.6	45.2
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	-54.2%	-43.4%	-31.5%	7.0%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Harvey & Irene Curtail Growth

Hurricane's Harvey and Irma slammed into the south eastern US during 3Q17 having a material impact Osprey's units sales across in Texas, Florida and to a lesser extent Georgia.

These two weather events represent the first time in 100 years that two category 4 or worse storms hit the US mainland in the one year.

Hurricane Harvey was first. It impacted Houston, Texas from 25 August 2017 and dumped 50 inches (~140 cm) of rain over a 4 day period. The storm caused major disruption to essential services including water, power and sanitation. Thousands of people were forced into evacuation centres. It was also reported that more than 1m vehicles and thousands of homes were destroyed or severely damaged by floodwaters and other storm affects.

Fortunately the San Antonio region of Texas was not severely affected by the storm, however, normal hospital activities in the region were impacted for a number of days.

Hurricane Irma started a few days later and affected normal activities in Florida and Georgia in early to mid September.

We estimate the storms impacted the normal operating activities of hospitals in 6 of the 17 sales territories during the quarter. Most importantly these impacted some of the larger revenue drivers being San Antonio, Houston, Atlanta and the two reps in Florida. Collectively these sales territories represent 2/3rds of unit sales in previous quarters.

SALES IMPACT

We had expected unit sales for the quarter of 1,700 relative to the 1,241 reported. While it is difficult to estimate the impact of the storms, the company estimates a likely impact in the vicinity of 200 to 250 units in total, hence even allowing for the impact of Harvey and Irma, unit sales were below our forecast.

Osprey did not provided the same quantity of sales analysis by Territory for Q3 as in Q2, however, excluding the affected areas of the south and south east, the company estimates sales in other territories grew by ~40% which is consistent with prior periods.

Putting together these various snippets of information:

Figure 1 - Q2 v Q3 unit sales analysis (estimates for Q3)

	Actuals	Estimates		Implied
	2Q17	3Q17	Difference	Growth
South and South East	770	570	-200	-26%
Other Territories	379	671	292	77%
Unit sales - Actuals	1,149	1,241	92	8%

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

The resulting implied growth rate for other territories of 77% is not entirely consistent with the commentary, however, we are reasonably confident that markets outside of the south and south east grew significantly. San Antonio remained well above breakeven for the quarter, but Atlanta volumes dipped below breakeven – which is less than 225 for the quarter.

The company reported that all of the major buying hospitals in affected areas have returned to normal activities, however, some of the newer hospital clients remain affected in the early part of 4Q.

Figure 2 - Summary of key reporting data

	1Q16	2Q16	3Q16	4Q16	1Q17	2Q17	3Q17
Total Unit sales	245	334	446	636	812	1,149	1,241
Sequential qtr growth	-	36%	34%	43%	28%	42%	8%
Revenues (US$'000)	87	119	156	223	290	408	441
Purchasing hospitals	27	29	39	45	55	75	83
Average unit sale per rep/month							
San Antonio	43	60	65	79	105	121	NR
Atlanta	6	28	39	47	78	91	NR
All other territories	na	na	3	5	5	11	NR

SOURCE: COMPANY DATA

SALES FORCE DEVELOPMENT

There are presently 17 sales reps and 5 clinical specialists covering the country. The appointment of a clinical specialist represents an important step in development of a sales territory as these individuals have responsibility for increasing the level of penetration within existing hospitals, somewhat freeing up the sales rep to pursue new business.

Following the successful capital raise, the company will continue to expand the sales force with the appointment of 4 new reps and 2 new clinical specialists. These additions are consistent with our long term revenue forecast and growth in the sales force.

We expect the company will continue to add new reps over the course of FY18 building to a total sales force of 35 to 40 inclusive of clinical specialists by the end of 2018.

FURTHER ADJUSTMENTS TO SHORT TERM REVENUE FORECASTS

Normal quarterly growth appears set to resume in 4th qtr. On a YTD basis unit sales are 3,202. The full year forecast is for 5,332 units. While this implies a very strong final quarter, the combination of some pent up demand from the south and south east together with other organic growth may yet see this target met.

The ongoing role out of the sales force will support future long term growth in revenues. Revenues for 3Q17 were clearly impacted by adverse weather events, however, allowing for this item, the prior 6 quarters show a somewhat consistent growth trajectory of between 28% to 43%.

Projecting a quarterly compound growth rate of 30% over a rolling twelve months commencing from 4Q17 equates to total unit sales over the period of ~10,000 units. Adopting the same growth rate for calendar 2018 and unit sales are estimated at ~14,000 units.

In our view these would be disappointing outcomes as we expect all 17 current sales territories to be better than break even (on average) in calendar 2018. 17 territories at an average of 75 units per months equates to ~15,300 units. Our current forecast is for 26,640 units, however this also assumes 28 sales reps.

While Osprey has not met our forecast unit sales to date, it continues to make good progress. The forward looking indicators continue to improve including the number of purchasing hospitals. As the sales base broadens the likelihood of future weather events may impact a particular quarter should decline. In addition, at the upcoming Transcatheter Cardiovascular Therapeutics conference, there will be over three hours of podium presentations for Dyvert Plus. Dyevert has a presence in only a fraction of the thousands of potential hospital customers in the US, hence there remains a long growth pathway.

Figure 3 - Summary of earnings changes

	2017			2018			2019		
	Old	New	% Change	Old	New	% Change	Old	New	% Change
Device sales	6,461	5,332	-17%	30,240	26,640	-12%	85,800	67,440	-21%
US$m									
Revenues	2.3	1.9	-18%	10.6	9.3	-12%	29.8	23.6	-21%
EBITDA	-13.0	-14.1	-9%	-7.7	-7.8	-1%	4.7	2.0	-58%
NPAT	-12.9	-14.2	-10%	-7.3	-7.9	-8%	5.1	1.9	-63%
EPS	-5.0	-4.4	12%	-2.8	-2.3	17%	2.0	0.6	-72%

SOURCE: BELL POTTER SECURITIES ESTIMATES

In FY17 we have further reduced revenue expectations reflecting lower than expected volumes in 3Q17. This has a flow on effect to subsequent year earnings. Nevertheless revenues continue to build each quarter. Valuation is amended to $0.43 from $0.53 following dilution from the recent capital raise and earnings downgrades.

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 Medical
as at 18 October 2017

Recommendation	Hold
Price	$0.40
Valuation (12 months)	$0.43

Table 1 - Financial summary

Profit & Loss (US$m)	FY15	FY16	FY17e	FY18e	FY19e
Year Ending December					
Device unit sales	430	1,661	5,332	26,640	67,440
Net revenue from product sales	0.2	0.6	1.9	9.3	23.6
COGS	-0.4	-0.7	-1.8	-3.7	-5.0
Gross profit	-0.2	0.3	0.1	5.6	18.5
GP margin	0%	50%	0%	60%	79%
R&D incentive/Upfront receipts	-	-	-	-	-
Total revenues	**0.2**	**0.6**	**1.9**	**9.3**	**23.6**
Other expenses	**-12.0**	**-11.4**	**-14.3**	**-13.4**	**-16.6**
EBITDA	**-12.2**	**-11.6**	**-14.1**	**-7.8**	**2.0**
D&A	0.0	-0.1	-0.1	-0.1	-0.1
EBIT	-12.2	-11.7	-14.2	-7.9	1.9
Sundry income	0.1	0.0	-	-	-
Pre tax profit	-12.2	-11.7	-14.2	-7.9	1.9
Tax expense	-	-	-	-	-
NPAT- normalised	-12.2	-11.7	-14.2	-7.9	1.9
Net abnormal items	-	-	-	-	-
Reported NPAT	-12.2	-11.7	-14.2	-7.9	1.9

Cashflow (US$m)	FY15	FY16	FY17e	FY18e	FY19e
Gross cashflow	-11.6	-10.5	-15.1	-8.4	1.1
Net interest	0.3	0.0	0.0	0.0	0.1
Tax paid	0.0	0.0	0.0	0.0	0.0
Operating cash flow	-11.4	-10.5	-15.1	-8.4	1.2
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	-15.3	-8.6	1.0
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
Dividends paid	0.0	0.0	0.0	0.0	0.0
Change in cash held	0.4	10.1	10.2	(8.6)	1.0
Cash at beginning of period	11.3	11.8	21.8	31.9	23.3
Cash at year end	11.8	21.8	31.9	23.3	24.3

Balance Sheet (US$m)					
Cash	11.8	21.8	31.9	23.3	24.2
Receivables	-	0.1	0.4	2.2	5.4
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	33.4	26.6	30.9
Trade payables /accruals	1.0	1.1	0.5	1.6	3.9
Other liabilities	-	-	-	-	-
Debt - interest bearing debt	-	0.1	0.1	0.1	0.1
Total Liabilities	1.0	1.2	0.6	1.7	4.1
Net Assets	11.6	21.6	32.8	25.0	26.8
Share capital	64.8	86.5	112.0	112.0	112.0
Retained earnings	(53.2)	(64.9)	(79.1)	(87.0)	(85.1)
Reserves	-	-	-	-	-
Shareholders Equity	11.6	21.6	32.8	25.0	26.8

Valuation Ratios (US$m)	FY15	FY16	FY17e	FY18e	FY19e
Reported EPS (cps)	-8.3	-6.2	-4.4	-2.3	0.6
Normalised EPS (cps)	-8.3	-6.2	-4.4	-2.3	0.6
EPS growth (%)	19%	-26%	29%	47%	na
PE(x)	**-4.8**	**-6.5**	**-9.1**	**-17.3**	**71.9**
EV/EBITDA (x)	-7.3	-7.7	-6.4	-11.6	45.2
EV/EBIT (x)	-7.3	-7.7	-6.3	-11.4	47.6
NTA (cps)	7.4	8.3	9.6	7.3	7.9
P/NTA (x)	5.4	4.8	4.2	5.5	5.1
Book Value (cps)	7.5	8.4	9.7	7.4	7.9
Price/Book (x)	5.3	4.8	4.1	5.4	5.1
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%	-6%	1%
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	-	-	-	240
USA	1,661	6,461	26,640	67,200
Australia/Asia Pacific	-	-	-	-
Total unit sales	**1,661**	**6,461**	**26,640**	**67,440**
Average revenue per sale US$'000	352	350	350	350

Half Year Earnings Split	1H16	2H16	1H17e	2H17e
Unit sales	590	1,071	1,961	3,371
Revenues	0.2	0.4	0.7	1.2
EBIT	-6.1	-5.6	-6.7	-7.5
NPAT	-6.1	-5.6	-6.7	-7.5

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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