BELL POTTER

31 August 2016

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

Analyst
John Hester 612 8224 2871

Authorisation
TS Lim 612 8224 2810

Osprey Medical (OSP)

DyeVert Plus Now Imminent

Recommendation
Buy (unchanged)
Price
$0.345
Valuation
$0.53 (unchanged)
Risk
Speculative

GICS Sector

Healthcare Equipment and Services

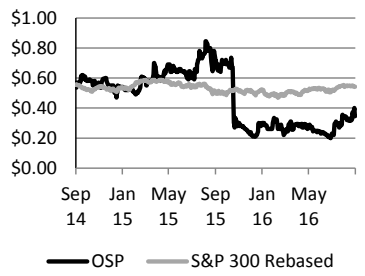
Expected Return	
Capital growth	**53.6%**
Dividend yield	**0.0%**
Total expected return	**53.6%**

Company Data & Ratios	
Enterprise value	**$32.1m**
Market cap	**$66.5m**
Issued capital	**192.7m**
Free float	**100%**
Avg. daily val. (52wk)	**$68,000**
12 month price range	**$0.19 - $0.78**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.35	0.25	0.75
Absolute (%)	-1.43	40.82	-54.00
Rel market (%)	-0.03	39.02	-59.13

Absolute Price



SOURCE: IRESS

1H16 Result Summary

The company reported revenues of US$0.2m and operating expenses of US$5.9m both of which were in line with our forecast.

Osprey piloted its commercialisation efforts in San Antonio, Texas starting in early 2015. This territory passed an important milestone in June 2016 when it achieved profitability for the first time by exceeding the breakeven point of 75 units. Unit sales have continued to grow in each quarter and based on the run rate achieved in June together with the ongoing growth, we remain confident the company will meet our revenue forecast of US$0.6m for FY16.

Following the completion of its A$28m capital raise Osprey is in the process of hiring six additional sales reps to take the total in the United States to 15. An additional five are planned for 4Q16.

This note provides a high level overview of the recent Best Practice Statement in the Cardiac Catheterisation Laboratory as issued by the Society for Cardiovascular and Angiography Interventions in the USA. In respect of percutaneous coronary interventions (PCI), the Best Practice Statement includes recommendations for setting of threshold limits, real time monitoring and recording of contrast use.

We also review the key features of DyeVert Plus – the next generation of the DyeVert system which incorporates improved features for calculating thresholds, monitoring the use of contrast during the PCI procedure and accurately recording the contrast use.

We believe the combination of the modified Best Practice Statements together with these improved feature in DyeVert Plus significantly strengthens the business case for the widespread adoption of the Dyvert and Dyvert Plus technology.

Maintain Buy Rating, Valuation Remains $0.53

There are no significant changes to our earnings forecast. DCF valuation is maintained at $0.53. We maintain our Buy rating.

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	-1.8
EPS growth %	19%	-42%	-19%	-55%
PER (x)	-4.1	-7.1	-8.8	-19.5
FCF yield (%)	-22%	-12%	-12%	-5%
EV/EBITDA (x)	-4.8	-5.3	-5.7	-12.0
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	0.0%	-38.2%	-54.8%	-34.3%

SOURCE: BELL POTTER SECURITIES ESTIMATES

DyeVert Plus Will Help Drive Growth

Summary Financial Results – 1H16

The key points from the 1H16 financials were as follows. Note that at all figures are quoted in US$.

- Revenue of $206K representing approximately 580 unit sales. Revenues were in line with the previous company updates on sales performance.
- Operating expenses of $5.9m – approximately 3% lower than pcp, however, there were significant changes in the mix of the spending. Sales and marketing expenses increased by ~$1m to $1.7m reflecting the additional selling staff hires and the expenditure associated with attendance at major clinical conferences. Clinical and regulatory expense declined by $1.4m to $1m reflecting the completion of the clinical trial program earlier in the year.
- R&D expense was $1.7m for the half. The company will have an ongoing R&D function at approximately the same level as the first half expenditure.
- The net operating loss was $6.1m with net cash outflow from operations of $5.7m.

Looking forward we expect sales and marketing expense will increase significantly in 2H16 as the company expands the sales force and continues to market the Dyvert technology in new markets around United States.

Figure 1 - Summary of earnings changes

	2016			2017		
	Old	New		Old	New	
Unit sales	1,800	1,800	% change	12,000	12,000	% change
US$m						
Revenues	0.6	0.6	5.0%	4.2	4.2	0.0%
EBITDA	-10.6	-11.0	3.6%	-10.4	-10.3	-0.6%
NPAT	-10.2	-10.6	3.8%	-10.0	-9.9	-0.6%
EPS	-4.3	-4.9	12.9%	-4.2	-3.9	-6.9%

SOURCE: BELL POTTER SECURITIES ESTIMATES

There are no significant changes to the earnings model. We had previously allowed for the capital raise. The company raised A$28m (~US$20m) at 28cps in July 2016. Following the capital raise Osprey has approximately US$25.8m in cash at the end of July. We believe this will be sufficient to fund the business through to its breakeven point in FY19.

We expect 2H16 revenues of approximately $0.4m driven by increased market penetration. Osprey has now had 8 sales reps in the field since approximately 1 March. There is a significant lag of 4 to 5 months between starting a rep in a new territory and generating first sales. The time lag is generally a reflection of the numerous regulatory and ethics hurdles associated with the adoption of new medical devices. Accordingly we expect revenue generation from the 8 existing reps to accelerate in 2H16.

Osprey is now in the process of recruiting additional sales reps for 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. The company intends to hire a further 5 reps in 4Q16.

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 $6.4m.

Regulatory Guidelines Update

The leading clinical authority for coronary intervention in the US is the Society for Cardiovascular and Angiography Intervention (or SCAI).

In April 2016 the SCAI updated its expert consensus statement – Best Practice in the Cardiac Catheterisation Laboratory (CCL). The document provides a consensus opinion on best practice as goals for the CCL.

It is expected that regulators, accreditation organisations, hospitals, health systems and administrators will reference this document for process improvement and standardisation.

The key points as far as Osprey is concerned are:

- **Patients with baseline renal insufficiency (estimate glomular flow rate < 60 mL/min/1.73m^2) and or elevated risk scores are at increased risk of developing contrast induced neuropathy (CIN).** The only strategies consistently shown to reduce the risk of CIN are hydration and minimising the contrast dose.
- **The contrast dose should be monitored**, and risk scores can be helpful in identifying a suggested limit. One tool uses the ratio of contrast volume to creatinine clearance, with a ratio of contrast volume /creatinine clearance > 3.7 as predictive of renal injury.
- **Total contrast administered to the patient must be monitored in real time** and limited as clinically possible. A maximum contrast volume of 3.7x the eGFR can be used as the upper limit of acceptable contrast dose during a single procedure to help limit the risk of CIN. CCL staff should inform physicians when these limits have been reached.
- **All elements of the procedure should be recorded** onto an electronic record that documents the procedure and the events that took place.

DyeVert Plus

Not by coincidence, these highlighted elements lend themselves to the new features of DyeVert Plus which was discussed by the company for the first time in detail following the release of the half year result.

DyeVert Plus is the same Dyvert technology now with improvements for:

- predetermined threshold volumes;
- real time monitoring of contrast use including alarms to warn theatre staff when the threshold limit is approaching; and
- recording of contrast volume use. The system includes embedded, single use blue tooth technology to create a wireless connection between the smart syringe, the DyeVert Plus Module and the new display unit (see figure 2).

These three features re-inforce the key selling points of the DyVert system as the only FDA approved medical device to reduce contrast use, preserve image quality and reduce reflux. These features will port across to the DyeVert Plus which is expected to launch in the US in early 2017.

The new features of DyeVert Plus use standard Bluetooth technology which does not affect the operation of the device itself. We do not expect the modifications will draw the attention of the FDA and even if there were some questions asked, the company will continue to sell the existing Dyvert System until such time that DyeVert is approved.

Ongoing sales of the Dyvert system will not be affected in the lead up to the introduction of Dyvert Plus. Dyvert is a single use system, often used in emergency situations.

Figure 2 - Images of DyeVert Plus

SOURCE: COMPANY DATA

DyeVert Plus will continue to sell for US$355 per patient. The smart syringe and DyeVert Plus module are the single use components. The monitor is re-useable which Osprey will supply to its hospital customers. The company continues to expect to generate an 80% gross profit margin of future revenues.

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 over the remainder of 2016 from the current nine to twenty. 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 31 August 2016

Recommendation	Buy, Speculative
Price	$0.345
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	28.0	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	17.3	(10.5)	(4.6)	5.0
Cash at beginning of period	11.3	11.8	29.0	18.6	14.0
Cash at year end	11.8	29.0	18.6	14.0	19.0

Balance Sheet (US$m)					
Cash	11.8	29.0	18.6	14.0	19.0
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	30.0	20.1	16.8	23.7
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	29.0	19.0	14.6	19.1
Share capital	64.8	92.8	92.8	92.8	92.8
Retained earnings	(53.2)	(63.8)	(73.8)	(78.2)	(73.7)
Reserves	-	-	-	-	-
Shareholders Equity	11.6	29.0	19.0	14.6	19.1

Valuation Ratios (US$m)	FY15	FY16e	FY17e	FY18e	FY19e
Reported EPS (cps)	-8.3	-4.9	-3.9	-1.8	1.8
Normalised EPS (cps)	-8.3	-4.9	-3.9	-1.8	1.8
EPS growth (%)					
PE(x)	**-4.1**	**-7.1**	**-8.8**	**-19.5**	**19.1**
EV/EBITDA (x)	-2.7	-3.0	-3.1	-6.6	7.8
EV/EBIT (x)	-2.7	-2.9	-3.1	-6.5	8.0
NTA (cps)	7.4	11.4	7.4	5.7	7.5
P/NTA (x)	4.6	3.0	4.6	6.1	4.6
Book Value (cps)	7.5	11.4	7.5	5.7	7.5
Price/Book (x)	4.6	3.0	4.6	6.0	4.6
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%	-12%	-5%	6%
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	1H16e	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.

Research Team

Staff Member	Title/Sector	Phone	@bellpotter.com.au
TS Lim	Head of Research	612 8224 2810	tslim
Industrials			
Sam Haddad	Industrials	612 8224 2819	shaddad
John O'Shea	Industrials	613 9235 1633	joshea
Chris Savage	Industrials	612 8224 2835	csavage
Jonathan Snape	Industrials	613 9235 1601	jsnape
John Hester	Healthcare	612 8224 2871	jhester
Tanushree Jain	Healthcare/Biotech	612 8224 2849	tnjain
Financials			
TS Lim	Banks/Regionals	612 8224 2810	tslim
Lafitani Sotiriou	Diversified	613 9235 1668	lsotiriou
Resources			
David Coates	Resources	613 9235 1833	showe
Peter Arden	Resources	613 9235 1731	parden
Associates			
Tim Piper	Associate Analyst	612 8224 2825	tpiper
Hamish Murray	Associate Analyst	61 3 9256 8761	hmurray

Bell Potter Securities Limited
ACN 25 006 390 7721
Level 38, Aurora Place
88 Phillip Street, Sydney 2000
Telephone +61 2 9255 7200
www.bellpotter.com.au