

Analyst
John Hester 612 8224 2871

Authorisation
Tanushree Jain 612 8224 2849

Osprey Medical (OSP)

34% Units Sales Growth in 3Q16

Speculative
Refer to key risks on page 4 and Biotechnology Risk Warning on page 7. Speculative securities may not be suitable for retail clients.

Recommendation

Buy (unchanged)

Price

\$0.385

Valuation

\$0.53 (unchanged)

Risk

Speculative

GICS Sector

Healthcare Equipment and Services

Expected Return

Capital growth	37.7%
Dividend yield	0.0%
Total expected return	37.7%

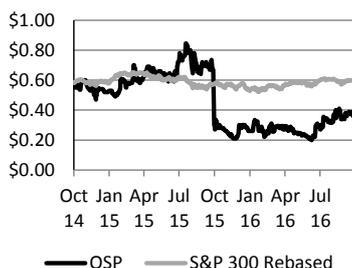
Company Data & Ratios

Enterprise value	\$66.7m
Market cap	\$99.2m
Issued capital	257.7m
Free float	100%
Avg. daily val. (52wk)	\$74,000
12 month price range	\$0.19 - \$0.67

Price Performance

	(1m)	(3m)	(12m)
Price (A\$)	0.35	0.31	0.70
Absolute (%)	13.04	25.81	-44.29
Rel market (%)	9.52	25.02	-48.30

Absolute Price



SOURCE: IRESS

Key Points from September Quarterly Update

The company achieved 34% unit sales growth across all territories for the quarter. Unit sales in the pilot sales territory of San Antonio continue to expand. There are now 8 additional territories under development and the cumulative unit sales of these now exceeds that of San Antonio.

San Antonio is on the cusp of its maiden quarter of profitability following two years of market development. Further, we understand some hospitals have indicated a reduction of up to 50% in the number of acute kidney injuries following adoption.

Sales momentum is continuing to accelerate. During the September quarter, the number of hospital buyers expanded by 33% to 39. There is a pipeline of 40 additional hospitals across the new sales territories currently evaluating the system.

Osprey continues to aggressively roll out its expansion plans in the US and restated its commitment to have 20 sales reps in place by year end. Following the recent hire of 2 new reps, there are now 11 reps in total.

The commentary from the company indicates that in leading hospitals who were amongst the first adopters in San Antonio, DyeVert is now used in up to 90% of cases involving angiogram for high risk acute kidney injury patients. This penetration rate has grown from an initial 20% and has gradually increased as more interventional cardiologists begin to use DyeVert. The company estimates the broader adoption rate is approximately 40%, albeit there are no published statistics to support this claim.

Maintain Buy Rating, Valuation Remains \$0.53

There are no significant changes to our earnings forecast. The DCF valuation is maintained at \$0.53 and we maintain our Buy rating. The number of hospitals using DyeVert continues to expand each quarter and it is reasonable to expect this will continue to grow. We conclude that the execution of the sales plan continues to progress well.

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	-1.7
EPS growth %	19%	-42%	-20%	-55%
PER (x)	-4.6	-7.9	-10.0	-22.1
FCF yield (%)	-19%	-11%	-11%	-5%
EV/EBITDA (x)	-6.1	-6.8	-7.3	-15.4
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	0.0%	-50.4%	-86.7%	-66.0%

SOURCE: BELL POTTER SECURITIES ESTIMATES

40 New Hospitals Evaluating DyeVert

Summary Financial Results – 3Q16

The key points from the 3Q16 cash flow statement and sales commentary were as follows:

- Units sales growth of 34% vs 2Q16. The company sold 446 DyeVert units in the quarter relative to 334 in prior quarter and approximately 579 for the entire 1H16.
- In the pilot sales territory in San Antonio, Texas unit sales continued to accelerate quarter on quarter at 9%. The company exceeded its breakeven target of 75 units per month in June 2016, however, for the September quarter units sales fell short of breakeven at 196 units. We expect the San Antonio sales territory will exceed the breakeven point for the December quarter.

Figure 1 - Quarterly Unit Sales and Samples **Figure 2 - Average Selling Price History**



	Q116	Q216	Q316
Unit sales	245	334	446
Revenues US\$'000	87	119	156
Average selling price US\$	355	356	349

SOURCE: COMPANY DATA

SOURCE: COMPANY DATA

- 70% of hospitals in the San Antonio sales area have now approved the product for use and have bought the product. This result has been achieved in only two years. We expect the take up rate to accelerate in new territories because the product now has the support of robust clinical data – which only became available in May 2016.
- Ex – San Antonio, unit sales were 250 units for the quarter and significantly exceeded sales in the original pilot market. This result covers 8 sales territories. New territories added this quarter include 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.
- OSP has recently hired sales reps number 10 and 11. The company remains on target to have 20 sales territories by the end of the calendar year.
- Free samples are provided to new hospital trialling the product. The volume of samples issued in the quarter continues to be a strong proxy for the subsequent unit sales growth. 40 new hospitals (across all territories) are in the evaluation to purchase cycle.
- 39 hospitals acquired product in 3Q16 representing an increase of 33% over the prior sequential quarter.

With 79 new hospitals either evaluating or having recently commenced use of the product we continue to anticipate ongoing growth in the final quarter of 2016.

Our unit sales target for the calendar year is 1,800 units. We estimate OSP has sold more than 1,000 units so far this year, hence the full year target is a stretch. While our timing may be a little aggressive there is no doubt that the sales momentum is building on multiple fronts. We anticipate the release of actual hospital savings (either in dollars or the number of CIN events) may be a major catalyst for future sales.

- Operating expenses for the quarter were US\$2.39m (2Q16: US\$2.95m). Most of the reduction in expenses is attributable to a US\$350K reduction in R&D expenditure. R&D expense had been elevated due to the development of the DyeVert Plus system in preceding months;
- We expect the run rate on staff costs will accelerate in the near term as the sales force expands to 20 by the end of the calendar year;
- Cash receipts from customers were US\$123K as compared to US\$113K in the prior sequential period;
- OSP raised net US\$21m from the issue of new securities in the period; and
- Closing cash was US\$24.4m.

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 US\$6.4m.

DYEVERT PLUS

DyeVert Plus is the latest release product from the company. Its key value add is real time monitoring against a pre-set limit for dye use. The product has received approval in the US and was recently submitted to the FDA for approval as supplementary approval. The FDA is expected to grant approval within 90 days of submission.

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. 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.

Table 1 - Financial summary

Profit & Loss (US\$m)						Valuation Ratios (US\$m)					
	FY15	FY16e	FY17e	FY18e	FY19e		FY15	FY16e	FY17e	FY18e	FY19e
Year Ending December											
Device unit sales	430.0	1,800	12,000	39,000	84,000	Reported EPS (cps)	-8.3	-4.9	-3.9	-1.7	1.8
Net revenue from product sales	0.2	0.6	4.2	13.3	27.2	Normalised EPS (cps)	-8.3	-4.9	-3.9	-1.7	1.8
COGS	-0.4	-0.3	-0.8	-2.7	-5.4	EPS growth (%)	19%	-42%	-20%	-55%	na
Gross profit	-0.2	0.3	3.4	10.6	21.7	PE(x)	-4.6	-7.9	-10.0	-22.1	21.6
GP margin	0%	50%	80%	80%	80%	EV/EBITDA (x)	-6.1	-6.8	-7.3	-15.4	18.0
R&D incentive/Upfront receipts	-	-	-	-	-	EV/EBIT (x)	-6.1	-6.8	-7.2	-15.1	18.4
Total revenues	0.2	0.6	4.2	13.3	27.2	NTA (cps)	7.4	8.5	4.6	2.9	4.7
Other expenses	-12.0	-11.3	-13.7	-15.5	-17.6	PNTA (x)	5.2	4.5	8.3	13.3	8.2
EBITDA	-12.2	-11.0	-10.3	-4.9	4.2	Book Value (cps)	7.5	8.6	4.7	2.9	4.7
D&A	0.0	-0.1	-0.1	-0.1	-0.1	Price/Book (x)	5.1	4.5	8.2	13.1	8.2
EBIT	-12.2	-11.1	-10.4	-5.0	4.1	DPS (cps)	-	-	-	-	-
Sundry income	0.1	0.5	0.5	0.5	0.5	Payout ratio %	0%	0%	0%	0%	0%
Pre tax profit	-12.2	-10.6	-9.9	-4.5	4.6	Dividend Yield %	0.0%	0.0%	0.0%	0.0%	0.0%
Tax expense	-	-	-	-	-	Franking %	170%	0%	0%	0%	0%
NPAT - normalised	-12.2	-10.6	-9.9	-4.5	4.6	FCF yield %	-19%	-11%	-11%	-5%	5%
Net abnormal items	-	-	-	-	-	Net debt/Equity	0%	0%	0%	0%	0%
Reported NPAT	-12.2	-10.6	-9.9	-4.5	4.6	Net debt/Assets	0%	0%	0%	0%	0%
Cashflow (US\$m)						Unit sales					
	FY15	FY16e	FY17e	FY18e	FY19e		FY16e	FY17e	FY18e	FY19e	
Gross cashflow	-11.6	-11.0	-10.8	-4.9	4.7	Europe	-	-	3,000	18,000	
Net interest	0.3	0.5	0.5	0.5	0.5	USA	1,800	12,000	36,000	66,000	
Tax paid	0.0	0.0	0.0	0.0	0.0	Australia/Asia Pacific	-	-	-	-	
Operating cash flow	-11.4	-10.5	-10.3	-4.4	5.2	Total unit sales	1,800	12,000	39,000	84,000	
Maintenance capex	-0.1	-0.2	-0.2	-0.2	-0.2	Average revenue per sale A\$'000	-	350	340	323	
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 acquisitions	0.0	0.0	0.0	0.0	0.0						
Proceeds from issuance	11.9	21.0	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	10.3	(10.5)	(4.6)	5.0						
Cash at beginning of period	11.3	11.8	22.0	11.6	7.0						
Cash at year end	11.8	22.0	11.6	7.0	12.0						
Balance Sheet (US\$m)						Half Year Earnings Split					
	FY15	FY16e	FY17e	FY18e	FY19e		1H16	2H16e			
Cash	11.8	22.0	11.6	7.0	12.0	Unit sales	590	1,210			
Receivables	-	0.1	0.5	1.7	3.4	Revenues	0.2	0.4			
Short term investments	0.3	0.3	0.3	0.3	0.4	EBIT	-6.1	-5.0			
Other current assets	0.1	0.1	0.1	0.1	0.1	NPAT	-6.1	-4.5			
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	23.0	13.1	9.8	16.7						
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	22.0	12.0	7.6	12.1						
Share capital	64.8	85.8	85.8	85.8	85.8						
Retained earnings	(53.2)	(63.8)	(73.8)	(78.2)	(73.7)						
Reserves	-	-	-	-	-						
Shareholders Equity	11.6	22.0	12.0	7.6	12.1						

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.

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	Isotiriou
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

The following may affect your legal rights. Important Disclaimer:

This document is a private communication to clients and is not intended for public circulation or for the use of any third party, without the prior approval of Bell Potter Securities Limited. In the USA and the UK this research is only for institutional investors. It is not for release, publication or distribution in whole or in part to any persons in the two specified countries. In Hong Kong this research is being distributed by Bell Potter Securities (HK) Limited which is licensed and regulated by the Securities and Futures Commission, Hong Kong. This is general investment advice only and does not constitute personal advice to any person. Because this document has been prepared without consideration of any specific client's financial situation, particular needs and investment objectives ('relevant personal circumstances'), a Bell Potter Securities Limited investment adviser (or the financial services licensee, or the representative of such licensee, who has provided you with this report by arrangement with Bell Potter Securities Limited) should be made aware of your relevant personal circumstances and consulted before any investment decision is made on the basis of this document. While this document is based on information from sources which are considered reliable, Bell Potter Securities Limited has not verified independently the information contained in the document and Bell Potter Securities Limited and its directors, employees and consultants do not represent, warrant or guarantee, expressly or impliedly, that the information contained in this document is complete or accurate. Nor does Bell Potter Securities Limited accept any responsibility for updating any advice, views opinions, or recommendations contained in this document or for correcting any error or omission which may become apparent after the document has been issued. Except insofar as liability under any statute cannot be excluded. Bell Potter Limited and its directors, employees and consultants do not accept any liability (whether arising in contract, in tort or negligence or otherwise) for any error or omission in this document or for any resulting loss or damage (whether direct, indirect, consequential or otherwise) suffered by the recipient of this document or any other person.

Disclosure of interest:

Bell Potter Securities Limited, its employees, consultants and its associates within the meaning of Chapter 7 of the Corporations Law may receive commissions, underwriting and management fees from transactions involving securities referred to in this document (which its representatives may directly share) and may from time to time hold interests in the securities referred to in this document.

Disclosure: Bell Potter Securities acted as Joint Lead Manager in the company's July 2016 capital raising and received fees for that service.

Biotechnology Risk Warning:

The stocks of biotechnology companies without revenue streams from product sales or ongoing service revenue should always be regarded as speculative in character. Since most biotechnology companies fit this description, the speculative designation also applies to the entire sector. The fact that the intellectual property base of a typical biotechnology company lies in science and not generally regarded as accessible to the layman adds further to the riskiness with which biotechnology investments ought to be regarded. Stocks with 'Speculative' designation are prone to high volatility in share price movements. Clinical and regulatory risks are inherent in biotechnology stocks. Biotechnology developers usually seek US FDA approval for their technology which is a long and arduous three phase process to prove the safety, effectiveness and appropriate application or use of the developed drug, and even after approval a drug can be the subject of an FDA investigation of subsequently discovered possible links between the drug and other un-previously diagnosed diseases. Investors are advised to be cognisant of these risks before buying such a stock including **Osprey Medical** (of which a list of specific risks is highlighted within).

ANALYST CERTIFICATION:

Each research analyst primarily responsible for the content of this research report, in whole or in part, certifies that with respect to each security or issuer that the analyst covered in this report: (1) all of the views expressed accurately reflect his or her personal views about those securities or issuers and were prepared in an independent manner and (2) no part of his or her compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed by that research analyst in the research report.