BELL POTTER

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Analyst
John Hester 612 8224 2871

Authorisation
Tanushree Jain 612 8224 2849

Osprey Medical (OSP)

Contrasting In Views

Speculative
Refer to key risks on page 4 and Medical Device Risk Warning on page 27. Speculative securities may not be suitable for retail clients

Recommendation
Buy (Initiation)
Price
$0.28
Valuation
$0.52 (initiation)
Risk
Speculative

GICS Sector

Healthcare Equipment and Services

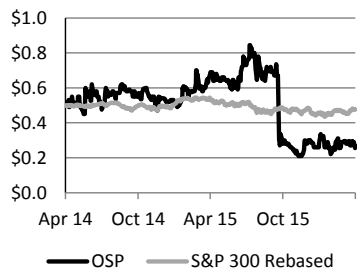
Expected Return	
Capital growth	**86%**
Dividend yield	**0%**
Total expected return	**86%**

Company Data & Ratios	
Enterprise value	**$27.4m**
Market cap	**$42.4m**
Issued capital	**154.2m**
Free float	**100%**
Avg. daily val. (52wk)	**$66,000**
12 month price range	**$0.19 - $0.85**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.29	0.26	0.65
Absolute (%)	-12.07	-1.92	-60.77
Rel market (%)	-14.74	-8.16	-49.07

Absolute Price



SOURCE: IRESS

Commercial Roll Out Proceeding

Osprey's DyeVert™ technology aims to reduce the rate of Contrast Induced Nephropathy (CIN) – a debilitating, potentially life threatening complication associated with kidney failure resulting from angioplasty and stenting procedures in patients with heart disease.

The company estimates there are up to 1.6m at risk procedures in the US each year which may benefit by using DyeVert™ technology. DyeVert has regulatory approval in the US for dye saving, preservation of image quality and reflux reduction. Notwithstanding these important indications, its recent pivotal trial across 578 patients showed no reduction in the rate of CIN events in the active arm of the trial compared to the control group.

Last week the company presented subgroup analysis from the trial. The impact of the AVERT system on patients with stage 3 kidney failure was profound. The incidence of CIN events reduced by 49.5% in this group. The data is statistically and clinically significant. In our view this sub group analysis is highly likely to draw the attention of hospitals and physicians alike. The sub group data was presented by the principal investigator of the AVERT study - Dr Roxana Mehran at a leading cardiovascular conference in the United States.

Irrespective of the new data, revenues have continued to accelerate since the announcement of the pivotal trial result. We expect revenues will exceed US$630K in CY2016 and grow aggressively in the short term. We also expect the company will require further capital from shareholders, to fund market development. .

Initiate With Buy Recommendation

Osprey is set to achieve significant revenue and earnings growth over the next decade. We initiate coverage with a Buy recommendation and valuation of $0.52.

Earnings Forecast

December Year End (US$)	FY15	FY16e	FY17e	FY18e
Revenues	0.2	0.6	4.2	13.3
EBITDA $m	-12.2	-10.6	-10.4	-6.1
NPAT (underlying) $m	-12.2	-10.2	-10.0	-5.7
NPAT (reported) $m	-12.2	-10.2	-10.0	-5.7
EPS underlying (cps)	-8.3	-4.3	-4.2	-2.4
EPS growth %	19%	-49%	-2%	-43%
PER (x)	-3.3	-6.4	-6.5	-11.5
FCF yield (%)	-27%	-16%	-16%	-9%
EV/EBITDA (x)	-2.2	-2.6	-2.6	-4.5
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	0.0%	-49.9%	-91.7%	-107.5%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Contents

Investment Case

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 six 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 seven 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, albeit the time delay is significant at approximately 4 months (which is the time generally required to pass through various approval processes at the hospital).

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 approximately 2020 when revenues are expected to exceed US$20m.

Key Risk Areas

A significant portion of company specific risk described in the 2012 prospectus has now dissipated. 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.

Financial Risk

The income statement forecast contained in this report forecasts the company will require further capital from shareholders in the short term in order to continue its operations in the United States. Without further capital, it is unlikely the company could continue with the current business model. Should the company be unable to raise sufficient capital, it is likely to adjust its business model or consider other measures. Either way, the rate of revenue generation may not meet our expectation and this would impact forecast earnings and the company's ability to continue as a going concern.

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.

Overview Of The Technology

Contrast Induced Nephropathy (kidney cell death) commonly occurs as a consequence of routine heart procedures such as angioplasty and stenting. Throughout these procedures, cardiologists must regularly inject dye (Contrast) into the heart so that the heart can be x-rayed in real time, to assist the cardiologist to guide catheters into the heart and identify blockages and/or place stents. As the injected dye leaves the heart, it enters the bloodstream and make its way to the kidneys where it can cause damage or acute kidney injury.

Approximately 25% of patients undergoing angioplasty or stenting are at high risk of contrast induced nephropathy (CIN) due to their pre-existing kidney disease. Current methods used for CIN prevention have had limited impact on reducing CIN risk.

AVERT is classified as a Class II medical device by the FDA.

CLINICAL TRIALS AND SYSTEM EVOLUTION

The initial pilot study of the original CINCOR system (as it was originally known) was conducted in Australia, Germany and New Zealand. It enrolled 41 patients across six sites. In this first generation product, access was via the jugular in the neck. Subsequent versions of the product have been approved with access via the femoral vein (in the thigh).

Most importantly the trial proved the system was safe. There were no serious adverse events related to the use of the device. The device was also highly effective in capturing and removing contrast as it exited the heart.

The pilot study facilitated the CE Mark approval as well as the Investigational Device Exemption (IDE) required before the company could commence a larger approval study in the US.

Subsequent to the CE Mark approval, but at about the same time as the US pivotal study began to enrol, the company made an important amendment to the CINCOR system when it introduced technology to reduce reflux.

'Reflux' is the term used to describe the large amount of dye that leaks out when injected into the coronary artery. Rather than travelling to the heart, refluxed dye disperses randomly and is of no use in the imaging and neither is it amenable for capture and removal, so the refluxed dye ultimately makes its way to the kidneys where it can contribute to CIN.

The reflux reduction technology was trialled in 20 patients where it was found to reduce the amount of dye injected by 37% compared to procedures that did not utilise the system. The reflux reduction technology was called AVERT.

The difference from CINCOR to AVERT was profound. CINCOR removed dye after it came out of the heart, and it involved more risk to the patient, as compared to AVERT which controls the volume of dye injected and is easier to use with less risk to the patient. Consequently the company abandoned CINCOR in favour of AVERT.

REGULATORY APPROVAL

The initial CE Mark was obtained in 2011. The reflux reduction technology was approved in Australia and Europe in 2012.

Initial plans to launch the product first in Europe were shelved in favour of gaining US FDA approval and this required the company to conduct a pivotal study that was completed in 2015.

Somewhat unexpectedly the FDA approved the AVERT system with the claim of, 'controlled delivery of dye' in August 2013 based on the earlier study conducted in Melbourne (and prior to completion of the US pivotal study).

The company persisted with the pivotal study in order to pursue the label claim of reduction in CIN events. Ultimately it was not able to prove this claim in the general population, however, the sub group analysis in the group with the most severe impairment of kidney function did show a large benefit. In this group the mean reduction in contrast induced acute kidney injury was 49.5%..

LATEST INNOVATION

In addition, the company recently introduced an LCD screen which allows the physician to monitor the amount of dye being used on a real time basis. The physician can input a pre-determined maximum volume of contrast intended for use in the procedure while monitoring progress as the procedure is completed. This amendment also allows for more accurate recording of the volume of contrast used.

The inclusion of the monitoring technology is known as AVERT Plus. Appendix IV contains a full description of the technology.

The **DyeVert System** further automates contrast modulation during manual injections as it self adjusts for catheter and contrast type without requiring user adjustments of the pin on the external control box. The product is easier to set up and provides more seamless integration into the catheter lab workflow. DyeVert received FDA approval in October 2015. It is also likely that DyeVert will shortly be updated to include the monitoring technology.

Competing Technologies

The June 2014 correspondence from the FDA which approves the AVERT System for marketing in the US states that the AVERT contrast modulation system is similar to the Medline Angiographic Control Syringe and the Acist Angiographic Injection System. Our research shows that both competitors are limited to controlling the infusion of contrast media. The competitors also facilitate more accurate recording of dye use, however, make no claim for reflux reduction, or image quality.

In our view the quantifiable claims for dye reduction, supported by data from a large randomised clinical trial provides the DyeVert technology with a competitive advantage. Furthermore, the yet to emerge sub group analysis from the AVERT study may further extend this advantage.

Customers

Images of the various components for the device are shown in Appendix IV. The US$350 sale price includes the single use Dyvert Disposable. Most of the other components are re-usable.

The payer for the device is the hospital, even though selling takes place to the physicians (Interventional Cardiologists).

AVERT Clinical Trial

This section includes a description of the US Pivotal study that reported results in October 2015. It is relevant because the trial did not meet the clinical endpoint of reduction in CIN events using the measure required by the FDA. In our view this was crucial to the share price reaction following the announcement which saw it decline by approximately 55%.

The product used in the AVERT trial was the AVERT system as described in the previous section (refer also to appendix IV).

AVERT was a **post approval clinical trial** designed to expand the label claim of the AVERT System. It was conducted with investigational device exemption (IDE). The key elements of the trial design were:

Patients were randomised on a 1:1 basis between

- Control arm - receiving standard of care (hydration only); or
- AVERT arm – treatment included the Avert system and hydration.

Patients were randomised PRIOR to receiving therapy. This is a classic parallel trial design of the type generally preferred by the FDA.

Patient population – 578 patients, all with chronic kidney disease and undergoing initial angiogram.

As the randomisation occurred prior to therapy, clinicians were not aware which patients would require only an angiogram (potentially showing no blockage) or Percutaneous Coronary Injection (PCI) or the severity/complexity of the PCI procedures. **This was a crucial factor in the outcome of the trial.**

We understand from the company, the randomisation did not result in an even distribution. The active arm of the trial received more patients requiring PCI, therefore, more contrast was used in this group relative to the control.

The primary endpoints of the trial were:

- Dye Savings; and
- Reduction in CIN events.

Secondary endpoints were reflux reduction and preservation of image quality.

Outcomes from Avert

The AVERT trial was successful in proving claims for:

Dye savings – 15% reduction in the Avert group;

Image Quality – no detectable difference between the two groups; and

Reflux Reduction – AVERT reduced dye usage without compromising image quality by reflux reduction.

The new expanded claims, including for dye savings, now enable physicians to comply with cardiology and radiology society guidelines (refer Appendix III) that urge physicians to use dye sparing approaches with at-risk patients.

The AVERT System is the only product to have a controlled, randomized, multi-center trial which proves a statistically significant reduction in dye while preserving image quality.

These FDA sanctioned claims were bridged to DyeVERT in Q1 2016.

The trial did not achieve a statistically significant reduction in contrast induced nephropathy.

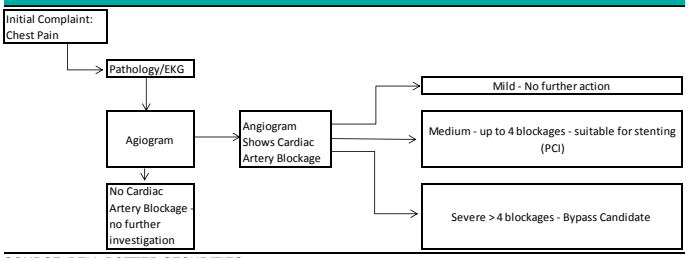
In our view this result was not well understood. The following table will assist readers understand why.

Figure 1 – AVERT clinical trial - Contrast Use

Procedure	Average (ml)	Range Dye Use (ml)
Angiogram	67	20 - 260
Percutaneous Cornonary Injection (PCI)	130	13 - 400

SOURCE: COMPANY DATA

Figure 2 - Clinical Pathway Overview for PCI



SOURCE: BELL POTTER SECURITIES

On average contrast use (or dye use) in PCI cases was 94% higher vs angiogram only cases. PCI also had up to a 30x differential in dye use vs a 13x differential for angiogram only (between the highest and lowest amount of Dye used).

In our view it is not unreasonable to deduce that as the AVERT arm of the trial had a skew of patients requiring a higher volume of contrast, the likelihood of achieving a reduction in CIN events was adversely effected.

Subsequent to these initial findings, the following data from the sub group analysis has been presented. The analysis compares the amount of dye used in the control arm vs the AVERT arm across different procedure types and is expressed as a percentage saving.

Figure 3 - Initial sub group analysis - AVERT v control

	Dye Savings
Angiogram only - no further intervetion	**8%**
All PCI	**23%**
PCI - 1 blockage	**15%**
PCI - 2 blockages	**31%**
PCI - 3 or more blockages	**46%**

SOURCE: BELL POTTER SECURITIES ESTIMATES

This initial subgroup data was released in late calendar 2015.

The analysis shows that in the most serious cases involving more than one cardiac arterial blockage, the dye savings were far greater than where no intervention was required (i.e. angiogram only). **In cases involving 3 or more blockages, the dye saving when using Avert was 46% compared to the control group.**

The overall dye saving in the AVERT arm was 15%, however, we believe this is an average across all procedures with no weighting for the complexity of cases involved.

SCAI Sub Group Analysis

Further subgroup analysis was presented last week at the Society for Cardiovascular Angiography and Interventions (SCAI) in Orlando, Florida.

The presentation highlighted the significance of post trial analysis directed by the Independent Physician Steering Committee on Contrast Induced Acute Kidney Injury (i.e. not the FDA).

The analysis looked at patients with pre-existing stage 3 kidney disease (refer to Appendix II).

The critical difference in this post hoc analysis was the alternative measure of serum creatinine from 0.3mg/dl to >0.5mg/dl. The standard measure for CIN is serum creatinine increase of >0.5mg/dl or >25% from baseline[1].

In the primary analysis, the FDA had insisted on a loose measure of CIN being changes of serum creatinine of >0.3mg/dl. Consequently the AVERT trial produced a high rate of CIN events. (150 CIN events from 578 patients – a rate of 26%).

By lifting the threshold for CIN events to serum creatinine changes >0.5mg/dl the number of CIN events fell from 150 to 90 events.

Figure 4 - Post hoc analysis of CIN using serum creatinine change >0.5mg/dl

Study Group	Patient numbers	Mean Reduction in CIN for AVERT vs control group
All patients	470	20.5%
Diagnostic (angiograpghy)	268	28.5%
PCI/Stenting	202	13.6%
Patients with stage 3 kidney disease	264	49.5%

SOURCE: COMPANY DATA

Across all patients, the AVERT group experienced a 20.5% reduction in CIN events.

In patients with moderate stage chronic kidney disease (stage 3) there were 264 patients across the control group and AVERT group. The mean reduction in CIN events was 49.5% in the AVERT group vs the control group (p value = .02).

We conclude that the AVERT system demonstrates a significant reduction in the rate of CIN events (using the standard measure). The rate of reduction in CIN events is higher amongst patients with stage 3 kidney disease.

[1] Barret et al. N Engl J. Med 354 (4) 379 - 86

Market Opportunity

The opportunity for Osprey Medical is directly related to the incidence of heart disease in key global markets.

There are certain patients undergoing an angiogram procedure that, due to prior history or other known conditions are identified as high risk, therefore the procedure should be conducted with the DyeVert System in order to minimise the use of contrast.

High risk patients are identified by the leading cardiac authorities and include any individual that has previously suffered a heart attack (known as a STEMI), have grade 3 or worse chronic kidney disease (CKD) or are diabetic.

Market analysis is difficult as most patients undergoing an initial angiogram have numerous co-morbidities including obesity, poor circulation, diabetes, high blood pressure, lower limb disease and many have a history of chronic cardiac disease. Nevertheless the incidence of CIN in the general population is about 7%, **but up to 50% in patients with several of these co-morbidities.**

The market estimate described below has the starting point of volume of angiograms (diagnostics) and PCI's conducted each year in the US and Western Europe. This data has been compiled by the company and is based on verifiable external evidence and carefully prepared estimates. We have verified key items in the estimate.

The company also used consultants to verify estimates on potential market size. A comparison of the two sets of data revealed a 25% to 30% gap between the company's estimate (which were higher) and the consultant estimates for the volume of angiograms and PCI's.

The results of the analysis are shown below:

Figure 5 - Overview of market size – company estimates

('000) of procedures		US	W. Europe	Total
US Coronary				
Diagnostic (angiogram)		2,326	1,809	4,135
PCI		1,238	1,209	2,447
Total Procedures		3,564	3,018	6,582
Diagnostic only (Angiogram)				
Stage 3-5 CKD	25%	582	452	1,034
Diabetes alone	18%	419	326	744
Total Angiogram Market		1,000	778	1,778
PCI only				
STEMI (prior heart attack)	20%	248	242	489
Other PCI	80%	990	967	1,958
Then of the 'others'				
CKD Stage 3-5	25%	248	242	489
Diabetes Alone	18%	178	174	352
Subtotal		426	416	842
Total PCI Market for DyeVERT		673	658	1,331
At risk patients for CIN		1,674	1,436	3,109

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

We conclude that in the US there are between 1.6 and 1.7m cases of coronary intervention each year where the patients may benefit from the use of DyeVert. The numbers are slightly lower in Western Europe (i.e. ~1.4m) for a total of ~3.1m procedures across both markets.

Using the lower estimate for starting volume of procedures, the total number of annual procedures in the US and Western Europe that may benefit from DyVert falls by 35% to 2.1m (from 3.1m).

While the difference between the two estimates is highly material, for the purposes of the financial forecast, the key point is that the market is very large. Further, we expect it will take the company approximately 4 to 5 years to reach revenues of $20m, representing a very modest penetration rate into this large market.

Finally our market size estimate does not include the market for lower limb procedures. This market alone is estimated at up to 1m procedures annually across the US and Europe.

Figure 5 below provides a high level sensitivity analysis of revenues for Avert/DyeVert based on the high and low estimates for the volume of Angiogram and PCI procedures.

Figure 6 - Revenue Sensitivity - PCI and Angiogram Market @US$400/procedure

		US	W. Europe	Total
Revenue sensitivity US$m	High	669	574	1,244
	Low	469	402	871

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

Overview of Co-morbidities

In Tsai et al, the investigators concluded the incidence of acute kidney injury following PCI was strongly related to the severity of baseline chronic kidney disease and history of heart disease including heart attack (i.e. STEMI in the literature).

The baseline characteristic of the 985K patients in the Tsai study are staggering.

- 29% - prior attack
- 36% - diabetic (not differentiated between T1, T2)
- 81% - high blood pressure
- 30% - chronic kidney disease (ranging from mild to severe).

CONCLUSION

There is significant evidence to indicate the potential market for the application of DyeVert technology is very large.

The best estimate for the number of angiograms and PCI's in the US and key markets in Western Europe that may benefit from Avery/Dyvert between 2.3m and 3.6m procedures annually. We estimate the value of revenues as between $871m and $1.2bn annually, albeit the actual revenues achieved by the company are subject to the broad adoption of the technology.

Financials And Valuation

Corporate History

- The company listed on the ASX in May 2012. There is no secondary listing on any other exchange.
- Osprey Medical is a US based company, headquartered in Minnesota.
- Financial statements are prepared in US$. All figures quoted in this report are in US$. OSP has a December year end for reporting.
- Financial statements are prepared under US GAAP. Under US GAAP 100% of R&D is written off as incurred.
- R&D investment will continue for the foreseeable future as the company continues a program for product development. In the short term these programs will focus on contrast reduction in modalities other than in the cardiac catheterisation setting i.e. CT scans for respiratory disease including congestive obstructive pulmonary disease (COPD).
- Since inception in 2005 through to December 2015, the company has spent ~$50m in development of the AVERT system and subsequent models.

Figure 7 - Key Financial Data

Key Financial Data US$m	FY14	FY15	FY16e	FY17e	FY18e
Device unit sales - global	0.0	430	1,800	12,000	39,000
US$m					
Revenue from device sales	0.0	0.2	0.6	4.2	13.3
Clinical and regulatory costs	2.8	4.3	2.0	2.0	2.0
Research and development	3.0	2.9	3.0	3.0	3.0
Other operating costs	3.8	4.8	5.9	8.8	11.7
Reported loss	**-9.7**	**-12.2**	**-10.2**	**-10.0**	**-5.7**
Net cash outflow from operations	**-8.9**	**-11.4**	**-10.1**	**-10.3**	**-5.6**
Opening cash balance	20.3	11.3	11.8	21.4	10.9
Cash raised from shareholders	0.0	11.9	20.0	0.0	0.0
Closing cash	11.3	11.8	21.4	10.9	5.2

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

As all research and development expenditure is written off as incurred, the company has a clean balance sheet with the only material asset being cash.

Based on the quarterly cash flow for the three months to 31 March 2016, the current annual run rate on expenses is approximately $11.6m inclusive of a sales force of 7 sales reps. The company has indicated its intention to expand to 20 sales reps by the end of 2016.

Each additional sales rep adds approximately $200K to the cost base.

Assuming a contribution (i.e. gross profit) of $280 from each unit sale, each sales person must generate at least 60 units per month to cover their individual cost. The company expects a gross profit margin of approximately 80% on product sales and this is consistent with other medical device companies.

We expect the run rate on operating costs to increase to approximately $14m in FY17. At that level breakeven is achieved at 49,000 device unit sales. We expect the company will pass the breakeven point in FY19.

The detailed revenue projections are included in this report in Appendix V.

At peak sales, we estimate 400 units per month per sales rep at approximately $350 each (indexed for CPI). This implies revenue per sales person of $2m at maturity, however, we allow for a long ramp up period to an average of 400 units per month with the company not achieving this target until 2022.

Our 11 year forecast has revenues peaking at $76m in 2026. We note that this implies a mere 8% market penetration rate (based on 1.7m annual PCI and angiograms involving higher risk patients) so there is very large upside to the revenue forecast.

Manufacturing

Osprey manufactures its products in-house compliant to FDA and ISO Regulations consisting of custom and catalogue components delivered from approved suppliers and converting them into finished goods through clean room assembly, packaging, and sterilization. Controlling these key processes assures maximum quality control, cost, and delivery. To date, Osprey has manufactured and shipped over 2,500 sterile devices to support the company's sales, clinical and R&D demands without missing a single delivery. Quality remains excellent with a field complaint rate under 2%. Capacity utilization is approximately 75% with manufacturing work cells designed to be scaled up efficiently and effectively. There are minimal capital requirements for production expansion.

Capital Requirement

Based on our projections, the company will require further capital from shareholders prior to becoming breakeven when revenues reach approximately $20m. The forecast assumes the company raises a further $20m in FY16.

Capital Structure

Osprey Medical is a US corporation incorporated in Delaware. For the purposes of the listing on the ASX, CHESS Depositary Interests (CDI's) are traded. Each CDI represents a beneficial interest in one half of an underlying share.

The legal title to the shares is held by the CHESS Depositary Nominees Pty Limited (CDN), a subsidiary of ASX. Holders of CDIs are entitled to all the economic benefits of the underlying shares, such as dividends (if any) as though they were holders of the legal title.

Figure 8 - History Of Capital Raising

		Offer Price (cents per CDI $A)	Amount Raised
			A$m
Mar-12	IPO	40	20
Oct-13	Private Placement	65	14
Mar-15	Private Placement	53	16
	Total		50

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

Figure 9 - Outstanding Options and Warrants as at 31 December 2015

	Total outstanding (CDI's)	Weighted average exercise price A$
Total options (m)	16.7	0.49
Inclusive of vested options (m)	12.4	0.45
Outstanding Warrants	320,000	

SOURCE: COMPANY DATA

Figure 10 - Substantial Shareholders

	CDI's (m)	Holding
CM Capital VT4A Pty Limited as trustee for CM Capital Venture Trust	34.0	22.1%
Brandon Capital Partners	24.8	16.1%
Kinetic Invesment Partner	8.7	5.6%

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

Valuation

We initiation coverage with a Buy recommendation and valuation of US$0.39 (A$0.52).

The primary valuation tool is a discounted cash flow model.

Figure 11 - Key Valuation Assumptions

Underlying Interest Rate	**5.0%**
Credit Spread	3.0%
Pretax Cost of Debt	8.0%
Assumed Corporate Tax Rate	30.0%
After Tax Cost of Debt	5.6%
Risk Free Rate	6.3%
Equity Beta	1.7
Equity Risk Premium	5.0%
Cost of Equity	14.8%
Gearing (D/D+E)	0.0%
Asset Beta	1.15
WACC	14.8%
Valuation Base Date	30-Jun-16
Explicit Forecast Period (Years)	10
Terminal Year (TY)	30-Jun-26
Terminal Growth Rate	2.0%
Terminal Year Multiple	6.9
Firm-based DCF Valuation	US$0.39
Franking Credits valued at	0%
IRR at Current Price	21.7%
IRR at DCF Valuation	14.8%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Board Of Directors

John Erb – Independent, Non Executive Chairman **(CDI's – Nil, Options – 448,839)**

Mr Erb is currently Chairman of the Board of Vascular Solutions, Inc., a NASDAQ listed company and has served on this board for 12 years. Vascular Solutions manufactures medical devices for the cardiology and interventional radiology markets. In 2015 the company had revenues exceeding US$147m.

Mr Erb has extensive experience at Board and Senior Executive level with other organisations in the United States, the vast majority of which are directly involved in medical device technologies. He has been Chairman of Osprey Medical since 2007.

Michael McCormick – President and CEO **(CDI's – 16,000, Options – 3.1m)**

Mr McCormick was appointed President & CEO of Osprey Medical in March 2010 and is responsible for the overall management and strategic direction of the Company reporting to the Board. He has 3 decades of experience in the medical device industry and President level experience with public and private medical device companies.

Neville Mitchell – Independent, Non Executive **(CDI's – 50,000, Options – 165,000)**

Mr Mitchell was appointed to the Board shortly after the company's ASX listing in July 2012. He is Senior Executive (CFO) at Cochlear Ltd and has significant experience in the field of medical devices in each of the major markets targeted by Osprey.

Andrew Jane – Non independent, Non Executive **(CDI's – Nil, Options – Nil)**

Mr Jane is a Managing Director with Talu Ventures which holds an interest in the company. Talu Ventures was founded in 2013 with a portfolio of investments formerly managed by CM Capital Investments.

He has more than 20 years of experience in the biomedical and IT industries. Following 4 years as a Project Manager at the CSIRO, Andy spent 5 years at AGEN Biomedical in various project management and business development roles. He joined Lake Technology, Sydney, in 1999, prior to its ASX listing, as Director of Business Development & Licensing. Lake Technology was later acquired by Dolby Labs in 2003. Other Directorships include Universal Biosensors Pty (ASX : UBI), SpeeDx Pty, Advent Pharmaceuticals Pty, Altiris Pharmaceuticals Inc and Piedmont Pharmaceuticals Inc.

Dr Chris Nave – Non Independent, Non Executive **(CDI's – Nil, Options – Nil)**

Dr Nave is a founding partner at Brandon Capital Partners which holds a substantial interest in the company.

He was previously Director of Commercialisation at the Baker IDI in Melbourne where he was responsible for the commercialisation of technologies developed at the Baker IDI and the Alfred Hospital.

The majority of the company's Board is not comprised of independent directors.

The Board is supported by a highly regarded Clinical Advisory Board.

Appendix I – Definitions

Coronary Angiogram – injecting dye (ICA) in heart arteries to diagnose (Diagnostic Angiogram) or treat (Percutaneous Coronary Intervention (PCI) or stenting) patients

In general for patients where the physician suspects that they have a blocked coronary artery the first step is to perform a diagnostic angiogram so the doctor can see if there is a blockage. There are 3 likely outcomes from this Diagnostic procedure:

- The diagnostic coronary procedure reveals NO blockages in any artery; good news for the patient. The Diagnostic procedure takes about 20 minutes and the total dye load for this patient averages 75ml. This occurs in ~50% of patients.
- The diagnostic coronary procedure reveals blockages in one or more arteries. They will immediately move to PCI and put stents in this patient. The Diagnostic + PCI procedure will take an hour and the average dye load is 150ml. If the patient needs 2 or 3 stents the amount of dye goes up >200ml as does total time of the case. This occurs in about 40% of patients.
- The diagnostic coronary procedure reveals so many blockages that the patient is not a candidate for stents and needs open heart bypass surgery. Total dye load for this patient averages 75ml. This occurs in about 10% of patients.

Percutaneous Coronary Intervention - (PCI) is also commonly known as angioplasty and is a non surgical procedure to treat narrowed coronary arteries. PCI is usually performed by an interventional cardiologist and normally involves the placement of a stent or scaffold. Percutaneous – simply means where access is via a needle/catheter as opposed to open.

Appendix II - Overview of Contrast Induced Nephropathy

In this section we draw extensively from the paper authored by Jeffrey Pasternack and Eric Williamson as published in Mayo Clinic Proceedings. This is a peer reviewed Medical Journal Sponsored by the Mayo Clinic[2].

Diagnostic tests such as MRIs, CT scans and angiograms are routinely used to assist doctors in the diagnosis of disease and injury. Osprey's AVERT Plus and DyeVert therapy is focussed only on angiogram and percutaneous coronary intervention (PCI).

Contrast agents have long been used in medical imaging procedures. The introduction of increasingly faster and more discriminating imaging techniques has resulted in the need for radiation-attenuating contrast agents that can be used in traditional radiographic imaging.

The most successful and widely applied contrast agents in use today are the iodinated contrast agents (ICAs). Iodine is a large ferrous molecule that is responsible for attenuation of the x-rays which facilitates images on the fluoroscopy screen. Fluoroscopy creates real time 2-D images of the body and facilitates angiograms and other interventional radiology procedures.

Osprey targets angiogram/ PCI procedures in which ICA is directly injected into the bloodstream (via intravascular administration) and cleared via the kidneys. In certain patients – most commonly those with chronic kidney disease (CKD), the contrast media fails to be excreted by the kidneys and can lead to further complications including re-admission to hospital, kidney failure, dialysis, heart attack and even death in extreme cases.

CONTRAST INDUCED NEPHROPATHY

Creatinine is a chemical waste product produced by muscle metabolism and to a smaller extent by eating meat. Healthy kidneys filter creatinine and other waste products from blood and these exit the body in urine.

The normal range of creatinine in the blood is about 0.84 to 1.21 milligrams per decilitre although this varies from men to women, and by age. Since the amount of creatinine in the blood increases with muscle mass, men usually have a higher creatinine level than do women.

A high serum level normally means the kidneys are not working well. It is not possible to undo kidney damage, therefore limiting progress of kidney disease is vital to overall patient survival.

Contrast-induced nephropathy (CIN) is a reduction in renal function after the administration of an ICA. The standard diagnostic criteria for contrast-induced nephropathy is a greater than 25% increase in baseline serum creatinine concentration within 3 days of receiving an ICA after other possible causes have been ruled out.

For patients with health kidneys, CIN often spontaneously resolves, however, for patients with impaired kidney function CIN events often do not resolve and may lead to further complication as discussed above.

[2] Mayo Clinic Proc. 2012 April; 87(4): 390-402

Glomular Filtration rate (GFR) is in important term in understanding kidney disease. It is a measure of the severity of kidney damage.

Kidney damage is classified in 5 stages according to eGFR:

Figure 12 - Kidney Damage by GFR scale

Stage	GFR*	Description
1	90+	Normal kidney function but urine findings or structural abnormalities or genetic trait point to kidney disease
2	60-89	Mildly reduced kidney function, and other findings (as for stage 1) point to kidney disease
3A 3B	45-59 30-44	Moderately reduced kidney function
4	15-29	Severely reduced kidney function
5	<15 or on dialysis	Very severe, or **endstage** kidney failure (sometimes call **established renal failure**)

* All GFR values are normalized to an average surface area (size) of 1.73m^2

SOURCE: THE RENAL ASSOCIATION

The AVERT trial post hoc analysis looked at patient in stage 3 i.e. those with moderately reduced kidney function.

INCIDENDCE RATES

The incidence of contrast-induced nephropathy is about 7% across all patients, but can be as high as 50% in those with pre-existing renal dysfunction. The worse the renal function, the higher the risk.

The risk for CIN can increase for people with diabetes, a history of heart and blood diseases, and chronic kidney disease (CKD). **For example, the risk of CIN in people with advanced CKD (glomerular filtration rate (GFR) below 30 mL/min/1.73m^2)**, increases to 30 to 40 percent. The risk of CIN in people with both CKD and diabetes is 20 to 50 percent.

It is estimated that approximately 75 million doses of ICAs are given worldwide each year.

RISK FACTORS FOR CIN

- Pre-existing renal dysfunction is the greatest risk factor for developing contrast-induced nephropathy, and the risk becomes greater with increasing baseline renal impairment.
- Other system disease including diabetes, hypotension, cardiac disease and use of drugs known to be toxic to the kidneys including non-steroid anti-inflammatory agents. The most comprehensive clinical trial examining these risk factors was conducted by Tsai et al over 985,737 patients[3].

INCREASED VOLUME OF CONTRAST AGENT INCREASES RISK

The nature of the ICA and volume administered can influence the risk of a CIN event. The use of high-osmolar ionic monomers, increases risk, however, it is still unclear whether there is a difference in the risk of developing contrast-induced nephropathy after the use of either nonionic dimers or nonionic monomers.

Investigators have not identified the cause of contrast-induced nephropathy. Suffice to say that it seems there is little doubt in the medical literature that ICA can causes decreased renal function. A detailed description of the theory is beyond the scope of this report.

[3] Tsai et al JACC Vol 7, No 1, 2014.

TREATMENT

- Avoid the procedure if at all possible – commonly not practicable;
- **Use the least amount contrast and weaker contrast solution.**
- Avoiding the concurrent administration of nephrotoxic drugs with ICAs; and
- Adequate hydration, and especially avoidance of dehydration, is critical for attenuating the risk of contrast-induced nephropathy.

ALTERNATIVE THERAPIES

Use of N-acetylcysteine, a free radical scavenger and renal vasodilator has produced mixed results in the prevention of contrast-induced nephropathy. The largest and most recent meta-analyses showed a benefit from the use of N-acetylcysteine in high-risk patients; however, there was considerable variability in both dosing and efficacy.

Low-dose dopamine (<2 µg/kg/per minute) increases renal blood flow and reduces sodium reabsorption, thus inducing diuresis. Use of low-dose dopamine to prevent contrast-induced nephropathy has demonstrated mixed results and may be harmful in patients with diabetes mellitus.

Hemodialys is effective at removing the ICA from circulation, but the use of hemodialysis after exposure to an ICA has not been shown to reduce the risk of the subsequent development of nephropathy in patients with preexisting renal insufficiency. This treatment is also very expensive.

Appendix III - Guidelines For Contrast Use

The leading cardiac authorities in the US are the American College of Cardiology (ACC) and the American Heart Association (AHA).

Their performance measures set the performance benchmark for practitioners and institutions that deliver cardiovascular services and provide tools to measure quality of care and identify opportunities for improvement.

These two bodies recently engaged a Task Force to develop measures to benchmark and improve the quality of percutaneous coronary intervention (PCI). PCI is also commonly known as angioplasty and is a non surgical procedure to treat narrowed coronary arteries. PCI is usually performed by an interventional cardiologist and normally involves the placement of a stent or scaffold.

In this task, the ACC/AHA Task Force partnered with the Society for Cardiovascular Angiography and Interventions (SCAI), the American Medical Association (AMA) and others in the development and review of these measures.

The 'performance measures' were published in the leading cardiology journal – Journal of the American College of Cardiology[4].

The performance measures contained in the journal article are extensively cross referenced to evidence based research.

Section 5.5 of the performance measures addresses renal function in PCI patients. It states:

- Assessment of renal function should be a standard part of pre-procedural work up. This should include glomerular filtration rate (GFR);
- Current guidelines recommend use of appropriate use of pre-procedural hydration in patients who have reduced GFR;
- The total amount of contrast volume administered to a patient should be documented;
- **The risk of contrast induced renal injury increases with increasing volume of contrast administered, and physicians should follow a principal of "as low as reasonably possible", especially in patients who have pre-existing renal dysfunction.**

The leading clinical work in this field was complete by Mehran[5]. This widely cited study is the benchmark piece of research in the prediction of CIN events after PCI and is well worthy for potential investors to read. All patients in the study had received routine hydration prior to the PCI procedure. (Profess Mehran was also the principal investigator in the AVERT study)

The key points of the study were as follows:

- The investigators sought to develop a simple risk score to predict CIN after PCI. A total of 8,357 patients were randomly assigned to a development and a validation data set.
- The development data set consisted of 5,571 patients. The investigators used statistical techniques to identify independent predictors of CIN with a p value <0.0001[6]. The eight identified variables included hypotension, congestive heart failure, chronic kidney disease diabetes, age >75 years, **volume of contrast**, inta-aortic ballon pump and anemia. They assigned a risk score for each risk

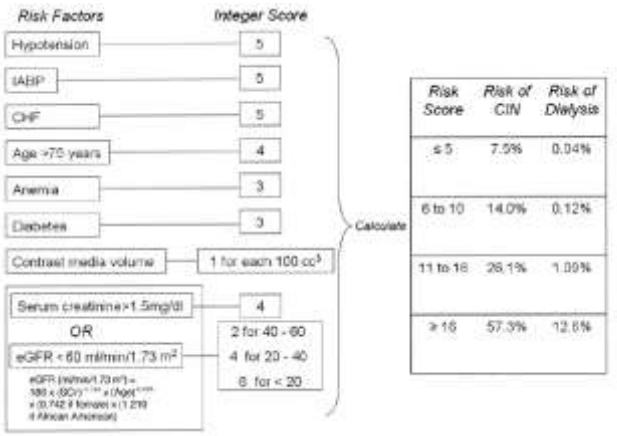
[4] JACC V 63, Issue 7 2014.

[5] Mehran et al JACC Vol 44, No 7 2004, October 6 page 1393-9

[6] P value <.05 is regarded as statistically significant. A p value of <0.0001 is highly statistically significant.

factor. (See figure 11). Each patient was scored on each of the risk factors to come up with a final risk score.

Figure 13 - Overview of Contrast Nephropathy Score



SOURCE: MEHRAN RESEARCH PAPER

Figure 14 - Scores in predictive data set v validation data set

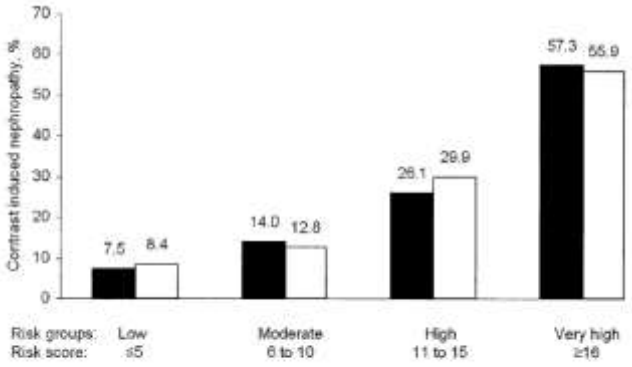


Figure 2. The contrast-induced nephropathy risk score derived from the development dataset predicted this complication in the validation set, as well. **Solid bars** = development dataset; **open bars** = validation dataset.

SOURCE: MEHRAN RESEARCH PAPER

For those patients with a high risk score the rate of CIN event increased exponentially. In the development group, for those patients with a risk score >16 the rate of CIN event was 57.3%.

The investigators then applied the risk scoring system to the validation dataset consisting of 2,786 patients. CIN events occurred in 386 of 2,786 (13%) patients in the validation set.

The investigators concluded that the CIN model demonstrated good discriminative power in the validation model (c=0.67, p<0.0001)[7].

The incidence of CIN by risk score assignment is depicted in figure 1, with significant trends across increasing scores for prediction of CIN.

The ability of the risk score to predict the rates of post PCI dialysis and one year mortality was further evaluated separately in the development and validation sets. Significant increases in the rates of dialysis and one year mortality were observed with increments of risk score in both sets.

The Mehran study is supported by other research including Gurm et al[8]. Their study in 22,912 patients showed a correlation between the volume of contrast use and CIN events and dialysis.

In practice, hospitals now commonly address this risk with pre-procedural assessment of renal function and identification of appropriate dosing threshold as a strategy for using the lowest possible amount of contrast.

Conclusion – there is ample literature published in highly regarded medical journals providing solid evidence based support of the association between the increase in volume use of contrast used in PCI procedures and renal injury.

[7] The probability that predicting the outcome is better than chance. Used to compare the goodness of fit of logistic regression models, values for this measure range from 0.5 to 1.0. A value of 0.5 indicates that the model is no better than chance at making a prediction of membership in a group and a value of 1.0 indicates that the model perfectly identifies those within a group and those not. Models are typically considered reasonable when the C-statistic is higher than 0.7 and strong when C exceeds 0.8.

[8] Gurm HS et al JACC 2011; 58 :907 - 914

Appendix IV – Overview Of AVERT, DyeVert Mechanism Of Action

AVERT™

The AVERT™ System is a dye volume reduction system used during angiographic coronary and peripheral procedures, as an adjunct to manual dye injections. The system is clinically proven to reduce excess dye volume (i.e. dye that is not needed for diagnostic or therapeutic purposes), accomplished by the reduction of excess reflux (i.e. "backwash" from the target artery into the aortic root) that would otherwise make its way to the patient's kidneys, while maintaining image quality.

The AVERT™ System consists of two components:

- An AVERT Contrast Modulator (reusable, non-sterile)
- An AVERT Modulation Reservoir (sterile, single use)

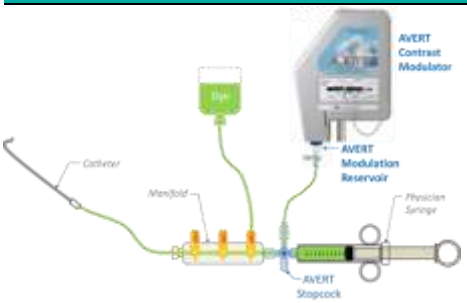
Figure 15 - AVERT

SOURCE: COMPANY DATA

Use of the AVERT System is as follows:

The stopcock of the Modulation Reservoir is placed between the physician's syringe and manifold, as part of a typical cath lab manual injection set up. The reservoir of the Modulation Reservoir is then inserted into the Contrast Modulator, as shown in the schematic below.

Figure 16 - AVERT Set Up



SOURCE: COMPANY DATA

Inclusion of the AVERT System creates a dual, "bifurcated" pathway for the injected dye to follow. One pathway is to the patient (through the catheter) and the other is to the AVERT System.

During an injection of dye, part of the dye volume is administered to the patient and the remaining excess portion of the dye is diverted to the AVERT System.

- The Contrast Modulator applies a load on the Modulation Reservoir. The load can be changed by moving the pin position on the Contrast Modulator, depending on dye injection requirements, such as catheter configuration and desired image opacity. The force acting on the Modulation Reservoir causes a resistance in the pathway to the AVERT System to proportionally match the resistance of the catheter configuration being utilized (i.e. pathway to the patient).
- The diverted dye is temporarily stored in the Modulation Reservoir, until the physician's injection is complete.
- Immediately after the injection, the diverted dye is returned to the physician's syringe. The returned dye can then be utilized for subsequent injections without wasting the dye.

The AVERT System is utilized throughout the procedure, saving dye on each injection.

DyeVert™

The DyeVert™ System is a dye volume reduction system used during angiographic coronary and peripheral procedures, as an adjunct to manual dye injections. The system is clinically proven to reduce excess dye volume (i.e. dye that is not needed for diagnostic or therapeutic purposes), accomplished by the reduction of excess reflux (i.e. "backwash" from the target artery into the aortic root) that would otherwise make its way to the patient's kidneys, while maintaining image quality.

The DyeVert™ System consists of one component:

A DyeVert Disposable (sterile, single use)

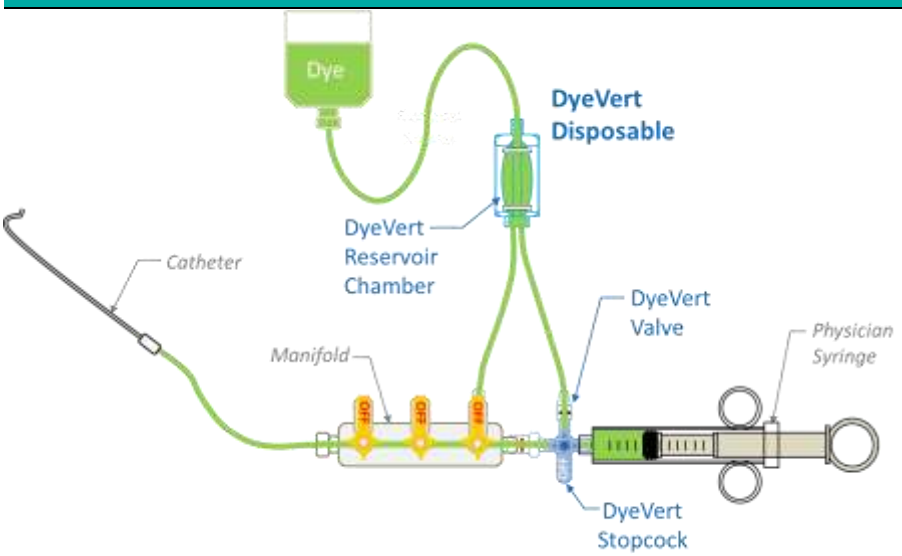
Figure 17 - DyVert - Single Use Device

SOURCE: COMPANY DATA

Use of the DyeVert System is as follows:

The DyeVert Stopcock is placed between the physician's syringe and manifold, as part of a typical cath lab manual injection set up, as shown in the schematic below.

Figure 18 - DyVert System Set Up



SOURCE: COMPANY DATA

- Inclusion of the DyeVert System creates a dual, "bifurcated" pathway for the injected dye to follow. One pathway is to the patient (through the catheter) and the other is to the DyeVert System.
- During an injection of dye, part of the dye volume is administered to the patient and the remaining excess portion of the dye is diverted to the DyeVert System.
- The *pressure-compensating valve* of the DyeVert (i.e. DyeVert Valve) responds to the pressure of the injection and automatically adjusts the resistance in the pathway to the DyeVert, proportionally matching the resistance of the catheter configuration being utilized (i.e. pathway to the patient). The valve adjustment occurs seamlessly without the need for the physician to change any device settings (such as moving a pin), offering an ease of use advantage over the AVERT System.
- The diverted dye is temporarily stored in the DyeVert Reservoir Chamber.
- Upon aspiration, the diverted dye is returned to the physician's syringe. The returned dye can then be utilized for subsequent injections without wasting the dye.
- The DyeVert™ System is utilized throughout the procedure, saving dye on each injection.

Appendix V - Detailed Revenue Forecast

	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026
United States											
PCI patients at risk with CKD co-morbidity	1,600,000	1,600,000	1,616,000	1,632,160	1,648,482	1,664,966	1,681,616	1,698,432	1,715,417	1,732,571	1,749,896
Revenue per unit US$	350	350	350	350	368	386	405	425	447	469	492
Average monthly unit sales per sales person	15	50	150	250	300	400	400	400	400	400	400
Revenue per sales person	63,000	210,000	630,000	1,050,000	1,323,000	1,852,200	1,944,810	2,042,051	2,144,153	2,251,361	2,363,929
Sales force	10	20	20	22	22	22	22	30	30	30	23
Unit sales	1,800	12,000	36,000	66,000	79,200	105,600	105,600	144,000	144,000	144,000	110,400
Unit sales US$	630,000	4,200,000	12,600,000	23,100,000	29,106,000	40,748,400	42,785,820	61,261,515	64,324,591	67,540,820	54,370,360
FX Rate	1	1	1	1	1	1	1	1	1	1	1
USD Revenues	630,000	4,200,000	12,600,000	23,100,000	29,106,000	40,748,400	42,785,820	61,261,515	64,324,591	67,540,820	54,370,360
Implied market penetration		1%	2%	4%	5%	6%	6%	8%	8%	8%	6%
EMEA											
PCI patients at risk with CKD co-morbidity	-	-	1,600,000	1,616,000	1,632,160	1,648,482	1,664,966	1,681,616	1,698,432	1,715,417	1,732,571
Revenue per unit EUR	200	200	200	200	210	221	232	243	255	268	281
Average monthly unit sales per sales person	-	-	50	150	150	150	150	150	150	150	150
Revenue per sales person	-	-	120,000	360,000	378,000	396,900	416,745	437,582	459,461	482,434	506,556
Sales force	-	-	5	10	10	10	10	10	10	10	10
Unit sales	-	-	3,000	18,000	18,000	18,000	18,000	18,000	18,000	18,000	18,000
Unit sales EUR	-	-	600,000	3,600,000	3,780,000	3,969,000	4,167,450	4,375,823	4,594,614	4,824,344	5,065,562
FX Rate	-	-	1.13	1.13	1.13	1.13	1.13	1.13	1.13	1.13	1.13
USD Revenues			678,000	4,068,000	4,271,400	4,484,970	4,709,219	4,944,679	5,191,913	5,451,509	5,724,085
Implied market penetration			0%	1%	1%	1%	1%	1%	1%	1%	1%
Total Revenue US$	0.6	4.2	13.3	27.2	33.4	45.2	47.5	66.2	69.5	73.0	60.1
Total unit sold	1,800	12,000	39,000	84,000	97,200	123,600	123,600	162,000	162,000	162,000	128,400
Average revenue per dose $		350	340	323	343	366	384	409	429	451	468

Osprey Medical
as at 9 May 2016

Recommendation	Buy, Speculative
Price	$0.28
Valuation	$0.52

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**	**-10.9**	**-13.8**	**-16.7**	**-18.9**
EBITDA	**-12.2**	**-10.6**	**-10.4**	**-6.1**	**2.8**
D&A	0.0	-0.1	-0.1	-0.1	-0.1
EBIT	**-12.2**	**-10.7**	**-10.5**	**-6.2**	**2.7**
Sundry income	0.1	0.5	0.5	0.5	0.5
Pre tax profit	-12.2	-10.2	-10.0	-5.7	3.2
Tax expense	-	-	-	-	-
NPAT- normalised	-12.2	-10.2	-10.0	-5.7	3.2
Net abnormal items	-	-	-	-	-
Reported NPAT	-12.2	-10.2	-10.0	-5.7	3.2

Cashflow (US$m)	FY15	FY16e	FY17e	FY18e	FY19e
Gross cashflow	-11.6	-10.6	-10.8	-6.1	3.4
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	-10.1	-10.3	-5.6	3.9
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	-10.3	-10.5	-5.8	3.7
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	11.9	20.0	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	9.7	(10.5)	(5.8)	3.7
Cash at beginning of period	11.3	11.8	21.4	10.9	5.2
Cash at year end	11.8	21.4	10.9	5.2	8.9

Balance Sheet (US$m)					
Cash	11.8	21.4	10.9	5.2	8.9
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	22.4	12.5	8.0	13.5
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	21.4	11.4	5.8	9.0
Share capital	64.8	84.8	84.8	84.8	84.8
Retained earnings	(53.2)	(63.4)	(73.4)	(79.1)	(75.9)
Reserves	-	-	-	-	-
Shareholders Equity	11.6	21.4	11.4	5.8	9.0

Last sale 09/05/2016	0.28
Recommendation	Buy (Spec)
Issued Capital	154.2
Market Cap	42.4

Valuation Ratios (US$m)	FY15	FY16e	FY17e	FY18e	FY19e
Reported EPS (cps)	-8.3	-4.3	-4.2	-2.4	1.4
Normalised EPS (cps)	-8.3	-4.3	-4.2	-2.4	1.4
EPS growth (%)	19%	-49%	-2%	-43%	-157%
PE(x)	**-3.3**	**-6.4**	**-6.5**	**-11.5**	**20.2**
EV/EBITDA (x)	-2.2	-2.6	-2.6	-4.5	9.7
EV/EBIT (x)	-2.2	-2.6	-2.6	-4.4	10.0
NTA (cps)	7.4	9.0	4.8	2.4	3.7
P/NTA (x)	3.7	3.1	5.8	11.6	7.4
Book Value (cps)	7.5	9.0	4.8	2.4	3.8
Price/Book (x)	3.7	3.0	5.7	11.4	7.3
DPS (cps)	-	-	-	-	-
Payout ratio %	0%	0%	0%	0%	0%
Dividend Yield %	0.0%	0.0%	0.0%	0.0%	0.0%
Franking %	0%	0%	0%	0%	0%
FCF yield %	-27%	-16%	-16%	-9%	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	571	1,229
Revenues	0.2	0.4
EBIT	-6.0	-4.7
NPAT	-5.9	-4.3

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
Sam Byrnes	Industrials	612 8224 2886	sbyrnes
Bryson Calwell	Industrials Associate	613 9235 1853	bcalwell
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