



Osprey Medical

Poised for Flight

Initiation of coverage

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Poised for Flight

Reducing Acute Kidney Injury

The contrast media or x-ray dye used in coronary angiograms (heart imaging) can cause Acute Kidney Injury (AKI)/ Contrast Injury Nephropathy (CIN), leading to impaired kidney function or in some patients, renal failure. The incidence of AKI is increasing, driven by the rising prevalence of diabetes, chronic kidney and cardiac diseases. Osprey (OSP.AX)'s DyeVert System device reduces dye volume used in angiograms by ~40% and thereby decreases the incidence of AKI.^{1,23} Medical guidelines support dye reduction to prevent AKI. DyeVert is FDA-cleared and has CE Mark for the EU.

Market Ready Product to Deliver Financial Turnaround

Ongoing product development has seen high R&D costs and limited market penetration impacting OSP's financial performance. This looks to change. With the expected US approval of its DyeVert Power XT in Q1CY21, OSP will effectively have coverage of the standard of care (SOC) angiogram testing systems and approval for the major markets.

The maturity of its product offering and global market approval has facilitated marketing partnerships with key industry players, including General Electric (GE) (NYSE:GE) the leader in the contrast dye market in CY20 and Premier Inc, a major US General Purchasing Organisation (GPO) in CY19.

Strong Support

Confidence in expected uptake of OSP's novel technology arises from the following;

- health guidelines by US and EU regulatory and medical organisations support dye reduction in angiograms
- commercial validation through GE and Premier Inc partnerships
- a lack of direct competition

Valuation, Risks and Sensitivities

MST values OSP.AX at CDI price of 3.4c based on a discounted cash flow (DCF) analysis. Agreements with GE and US Independent Sales Agents are expected to significantly grow OSP's market penetration. There is execution risk. The key forecast sensitivities include sales volumes to drive gross margin expansion from ~50% to ~60%. By MST forecasts, there is risk that OSP may need additional funding in FY23 if the forecast sales momentum is not achieved.

In MST's view, there is a strong case for acquisition if the market potential is realised. In our view, GE is a potential buyer. It will develop an indepth knowledge of the product and its potential. Elimination of administration costs would reduce operating costs by ~32% in FY24.

Osprey Medical (OSP.AX) is a US medical device company that is focused on improving outcomes in chronic kidney disease (CKD) patients by reducing contrast-induced acute kidney injury.

The maturation of its novel contrast dye reduction technology has opened significant growth potential. With development risk now passed, management must demonstrate its ability to execute its commercial strategy. In comparison to many other novel ASX-listed biotech stocks, OSP's risk profile is low.

Stock	ASX: OSP
Price	A\$0.021
Market cap	A\$34m

Company data

Net cash (Oct CY20)	A\$11.5m
CDI on issue	1,623m
Options and rights outstanding	942m
Code ASX	OSP.AX
Primary exchange	ASX

Next steps

CY21 DyeVert PowerXT to receive FDA approval for US market

CY21 BioCore sales to commence in US

CY21 GE sales coverage to increase

OSP share price (12 months)



Financial Summary

Osprey Medical

Year end 31 December

MARKET DATA

CDI Price	¢	2.1
52 week high / low	¢	5.6 - 0.9
Valuation (12 month forward)	¢	3.4
Market capitalisation	\$m	34.1
CDIs on issue	m	1,623
Options	m	942
Other equity	m	-
Potential CDIs on issue (diluted)	m	2,566
Potential shares on issue (diluted)	m	1,263

INVESTMENT FUNDAMENTALS	FY19	FY20E	FY21E	FY22E	FY23E
EPS Reported (undiluted)	¢ (8.4)	(2.6)	(0.9)	(0.4)	(0.0)
EPS Underlying (undiluted)	¢ (8.4)	(2.6)	(0.9)	(0.4)	(0.0)

Underlying EPS growth	%	n/m	n/m	n/m	n/m	n/m
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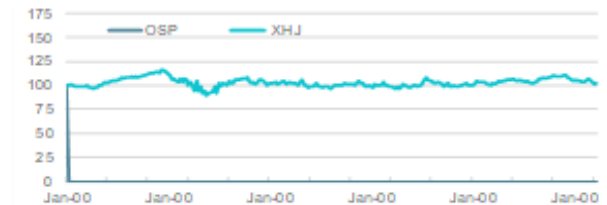
P/E Reported (undiluted)	x	n/m	n/m	n/m	n/m	n/m
P/E at Valuation	x	n/m	n/m	n/m	n/m	n/m

Dividend	¢	0.0	0.0	0.0	0.0	0.0
Payout ratio	%	0%	0%	0%	0%	0%
Yield (YIE/spot)	%	0.0	0.0	0.0	0.0	0.0
Franking	%	n/a	n/a	n/a	n/a	n/a
Gross Yield (YIE/spot)	%	0.0	0.0	0.0	0.0	0.0

KEY RATIOS (US\$)	FY19	FY20E	FY21E	FY22E	FY23E	
Forecast year end shares	m	216	812	1,338	1,338	1,338
Forecast year end CDIs	m	432	1,623	2,676	2,676	2,676
Market cap (YIE / Spot)	\$m	9.1	26.0	42.8	42.8	42.8
Net debt (cash)	\$m	(8.3)	(3.0)	(4.4)	1.0	1.6
Enterprise value	\$m	0.8	22.9	38.2	43.6	44.2
EV/Sales	x	0.2	14.3	6.7	3.3	2.1
EV/EBITDA	x	n/m	n/m	n/m	n/m	131.0
EV/EBIT	x	n/m	n/m	n/m	n/m	1,527.1
Net debt / Enterprise Value	x	(10.3)	(0.1)	(0.1)	0.0	0.0
Gearing (net debt / EBITDA)	x	0.5	0.2	0.5	(0.2)	4.7
Operating cash flow per share	¢	(7.8)	(2.6)	(1.0)	(0.4)	(0.0)
Price to operating cash flow	x	n/m	n/m	n/m	n/m	n/m
Free cash flow	\$m	(17.0)	(15.0)	(10.6)	(5.4)	(0.6)
Free cash flow per share	¢	(7.9)	(2.6)	(1.0)	(0.4)	(0.0)
Price to free cash flow	x	n/m	n/m	n/m	n/m	n/m
Free cash flow yield	%	n/m	n/m	n/m	n/m	n/m
Book value / share	¢	3.7	0.4	0.5	0.3	0.6
Price to book (NAV)	x	1.1	7.7	6.4	9.3	5.5
NTA / share	¢	3.7	0.4	0.5	0.3	0.6
Price to NTA	x	1.1	7.7	6.4	9.3	5.5
EBITDA margin	%	n/m	n/m	n/m	n/m	2%
ROE (Average Equity)	%	n/m	n/m	n/m	n/m	0%
ROA (EBIT)	%	n/m	n/m	n/m	n/m	n/m
Interest cover (EBIT / net interest)	x	n/m	n/m	n/m	n/m	(1)

DIMENSIONAL	FY19	FY20E	FY21E	FY22E	FY23E
US (In house sales)					
Units	11,200	4,770	9,000	12,000	15,000
Revenue / unit	327	335	344	352	361
Sales (US\$m)	3.7	1.6	3.1	4.2	5.4
US (ISA)					
Units	-	-	5,000	17,500	30,000
Revenue / unit	-	-	350	359	368
Sales (US\$m)	-	-	1.8	6.3	11.0
US (General Electric)					
Units	-	-	5,000	15,000	27,000
Revenue / unit	-	-	175	179	184
Sales (US\$m)	-	-	0.9	2.7	5.0
Total Sales (US\$m)	3.7	1.6	5.7	13.2	21.4
Gross margin (%)	52%	30%	44%	60%	61%
Total gross margin	1.9	0.5	2.5	7.9	13.1

12 month relative performance versus S&P/ASX Health Care Index



PROFIT AND LOSS (US\$)	FY19	FY20E	FY21E	FY22E	FY23E	
Total Revenue	\$m	3.7	1.6	5.7	13.2	21.4
COGS	\$m	(1.8)	(1.1)	(3.2)	(5.3)	(8.3)
Gross margin	\$m	1.9	0.5	2.5	7.9	13.1
Corporate costs	\$m	(19.9)	(14.8)	(12.3)	(12.4)	(12.8)
EBITDA	\$m	(18.0)	(14.3)	(9.8)	(4.5)	0.3
Depreciation & amortisation	\$m	(0.3)	(0.3)	(0.3)	(0.3)	(0.3)
EBIT	\$m	(18.2)	(14.6)	(10.1)	(4.8)	0.0
Net interest	\$m	0.2	0.0	(0.0)	(0.0)	(0.1)
Non-operating income	\$m	0.0	0.0	0.0	0.0	0.0
Pretax Profit	\$m	(18.1)	(14.6)	(10.1)	(4.9)	(0.0)
Tax expense	\$m	0.0	0.0	0.0	0.0	0.0
Minorities	\$m	0.0	0.0	0.0	0.0	0.0
Underlying NPAT	\$m	(18.1)	(14.6)	(10.1)	(4.9)	(0.0)

BALANCE SHEET (US\$)	FY19	FY20E	FY21E	FY22E	FY23E	
Cash	\$m	8.3	4.3	5.7	0.4	0.1
Receivables	\$m	0.5	0.2	0.7	1.7	2.7
Inventory	\$m	0.9	1.0	3.6	8.2	13.4
Other	\$m	0.1	0.1	0.1	0.1	0.1
Current assets	\$m	9.8	5.6	10.1	10.3	16.2
PPE	\$m	0.6	0.6	0.6	0.6	0.6
Goodwill	\$m	0.0	0.0	0.0	0.0	0.0
Other	\$m	0.5	0.4	0.4	0.4	0.4
Non current assets	\$m	1.0	1.0	1.0	1.0	1.0
Total Assets	\$m	10.8	6.6	11.1	11.3	17.2
Accounts Payable	\$m	1.1	0.5	1.7	3.9	6.4
Borrowings	\$m	0.0	0.0	0.0	0.0	0.0
Other	\$m	1.3	1.0	1.1	1.1	1.1
Current liabilities	\$m	2.4	1.5	2.8	5.0	7.5
Borrowings	\$m	0.0	1.3	1.3	1.3	1.6
Deferred tax liabilities	\$m	0.0	0.0	0.0	0.0	0.0
Other	\$m	0.4	0.4	0.4	0.4	0.4
Non current liabilities	\$m	0.4	1.7	1.7	1.7	2.0
Total Liabilities	\$m	2.7	3.2	4.5	6.7	9.5
Equity	\$m	122.9	132.6	144.6	144.6	144.6
Retained earnings	\$m	(114.8)	(129.4)	(139.5)	(144.4)	(144.4)
Reserves / Other	\$m	0.0	0.1	1.5	4.3	7.5
Shareholder's equity	\$m	8.1	3.4	6.6	4.6	7.7

CASH FLOW (US\$)	FY19	FY20E	FY21E	FY22E	FY23E	
EBITDA	\$m	(18.0)	(14.3)	(9.8)	(4.5)	0.3
Change in working capital	\$m	0.3	(0.4)	(0.5)	(0.5)	(0.6)
Net interest	\$m	0.0	0.0	(0.0)	(0.0)	(0.1)
Tax paid / Refund	\$m	0.0	0.0	0.0	0.0	0.0
Other	\$m	0.8	0.0	0.0	0.0	0.0
Operating cash flow	\$m	(16.9)	(14.7)	(10.3)	(5.1)	(0.3)
Stay in business capital expenditure	\$m	0.0	0.0	0.0	0.0	0.0
Growth capex	\$m	(0.1)	(0.3)	(0.3)	(0.3)	(0.3)
Net investment / Other	\$m	0.0	0.0	0.0	0.0	0.0
Investing cash flow	\$m	(0.1)	(0.3)	(0.3)	(0.3)	(0.3)
Change in Equity	\$m	0.0	9.7	12.0	0.0	0.0
Increase / (decrease) in borrowings	\$m	0.0	1.3	0.0	0.0	0.3
Dividend / other	\$m	0.0	0.0	0.0	0.0	0.0
Financing cash flow	\$m	0.0	11.1	12.0	0.0	0.3
Change in Cash / FX	\$m	(17.0)	(3.9)	1.4	(5.4)	(0.3)
Year end cash	\$m	8.3	4.3	5.7	0.4	0.1

Investment Thesis

It is time to have another look at Osprey Medical (OSP.AX). Its first generation product was approved in 2012. Ongoing R&D to develop a model to best match the clinicians' needs in a changing medical technology environment has impacted the company's financial performance. Limited market penetration and high costs have seen its earnings and consequently its share price, underperform. However, change is taking place. The 'coming of age' of OSP's medical device program is evidenced by recent partnerships with GE and Premier Inc. The sales volume growth from an extended marketing reach is expected to expand margins and drive earnings momentum.

Lower Risk, Meaningful Markets, Medical Backing

OSP's development program has been focused on the reduction of the amount of contrast dye used in cardiac and peripheral angiograms. The initial investment thesis is still valid:

Clinical Need - Excess dye can lead to serious, life-threatening renal complications.

Significant Markets -With the expected approval of OSP's DyeVert Power XT in the US in CY21, the DyeVert products will cover the standard angiogram systems and will be approved for all major global markets. Markets are significant with some 3.2m patients pa in the US and western EU at risk of AKI following angiograms.²

Support from Medical Authorities' Guidelines - There is no effective treatment to manage the renal complications from the angiogram dye. Medical associations including the American College of Cardiology, American Heart Association and EU Society for Cardiology recommend reduction of the dye used during the procedure. DyeVert Plus EZ is the only FDA approved dye reduction device.

No Direct Competition - OSP's DyeVert devices have no direct competition. It is the only FDA approved device to reduce dye in angiograms and not impact the quality of the imaging. OSP's commercial partners provide external validation.

What's Changed

With the launch of the DyeVert range, OSP's product development has matured with management only planning incremental R&D. The benefits are emerging already. OSP has announced a four-year agreement with GE. GE is the world's leader in contrast dye sales and will market DyeVert in the key ex-US markets. OSP has negotiated agreements with five US Hospital Group Purchasing Organisations (GPO), including Premier Inc, one of the largest. It has also started engaging Independent Sales Agent groups in the US to supplement its in house team. Market coverage will increase exponentially from FY21.

Valuation, Risks and Sensitivities

MST values OSP.AX at CDI price of 3.4c based on a discounted cash flow (DCF) analysis. Agreements with GE and US Independent Sales Agents are expected to significantly grow OSP's market penetration. OSP faces the usual commercial risks of medical products. There is also execution risk. The key forecast sensitivities include sales volumes to drive margin expansion from ~50% to ~60%. OSP. There is risk that OSP may need additional funding if the sales momentum is not achieved.

In MST's view, there is a strong case for acquisition if market penetration is demonstrated with GE be a potential buyer. Elimination of corporate overheads would benefit earning margins.

OSP has Solution to a Major Medical Need

Osprey Medical (OSP.AX)'s DyeVert technology offers a proven and approved system to reduce AKI, a potentially serious and expensive complication of cardiac and peripheral angiograms.

The Need: Cardiac Patients at Risk of Kidney Problems from Contrast Dye

Patients undergoing cardiac or peripheral angiograms or cardiac stenting angiograms require a contrast dye to be injected into the cardiac arteries to highlight any blockages or abnormalities. The body then filters the dye through the kidneys. Some 15-25% of patients undergoing angiograms have pre-existing poor kidney function or carry other risk factors such as diabetes or heart failure. Their compromised kidney function prevents filtration of the dye.

Renal Damage Relates to Volume of Contrast Dye

The uncleared dye can result in kidney damage. Referred to as AKI or CIN, it represents a serious medical concern. AKI typically develops within two to seven days of administration of iodinated contrast media.⁷ It can lead to minor loss of function to complete kidney failure requiring dialysis.^{3,8,9} In addition to increased mortality, patients with AKI have relatively higher incidences of other adverse outcomes including myocardial infarction, bleeding requiring transfusion, and vascular complications.¹⁰

While the mechanisms for the development of AKI are not fully understood, a number of studies have shown a relationship between the volume of the contrast dye used and the development of AKI following angiography and percutaneous coronary intervention (PCI) procedures.^{4,5,6}

How common is acute kidney injury?

The incidence rate of AKI reported in the literature is variable, ranging from 3% to 42% depending on the patient's comorbidities.^{11,12} Generally, it is agreed that 15-25% of angiography patients present with Chronic Kidney Disease (CKD). For OSP, the targeted global markets represent an estimated at 3.2m pa angiograms in patients who are at risk of AKI.²

What are the costs of acute kidney injury?

There are associated economic burdens to hospitals and payors resulting from increased length of stay and other factors. Longer periods of hospitalisation and readmission are common.^{15,16} AKI has been estimated to add approximately \$10,000 to the in-hospital cost of a patient undergoing PCI.^{17,18} Amin et al analysed PCI patients from Premier Inc's database representing data from 518 US hospitals in 2006-2015. The analysis showed a significant association between AKI and length of hospital stay with an estimated annual cost burden to be over US\$400m.¹⁷

The Solution: OSP's DyeVert Reduces Dye Use, Decreases Risk from Angiograms

The DyeVert device provides a medically and economically beneficial solution to reduce AKI.

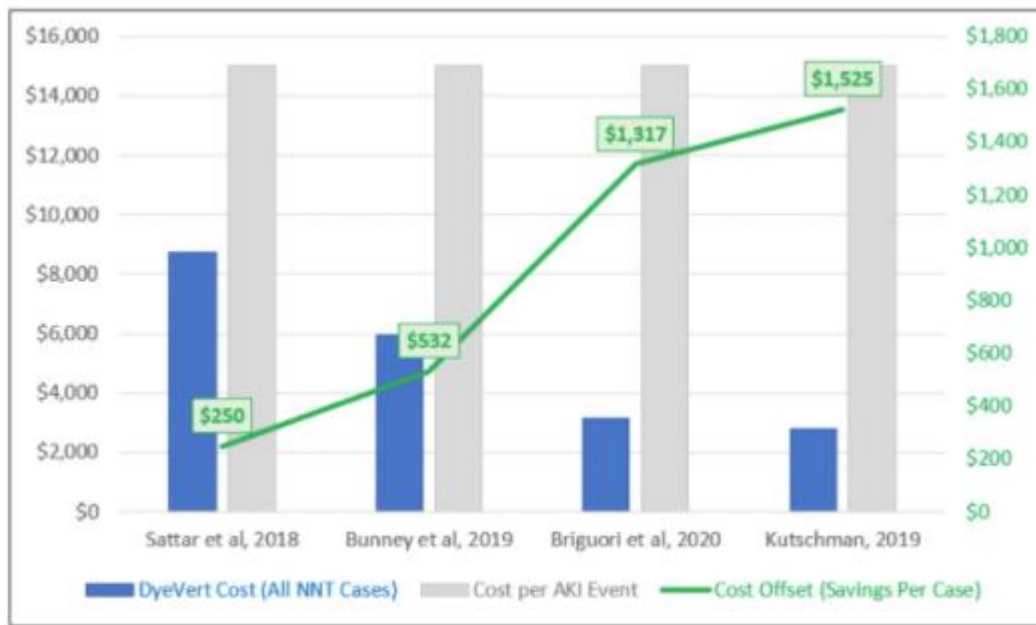
Medical benefits: reduced dye, with images unaffected

The DyeVert System reduces the dye used in the angiogram by ~40%, which has been shown to reduce AKI. OSP's DyeVert Plus Systems are the only FDA-cleared and CE Mark products proven to reduce contrast dye without affecting radiographic image quality. The company's newest product – the DyeVert Power XT, for use with automated contrast injectors – has CE Mark for the EU markets and the company expects FDA approval in early 2021.

Economic benefits: patient burden and reduced hospital costs

The economic perspective is also positive. At a cost of US\$350, the DyeVert System has been proven in clinical studies to reduce hospital costs associated with AKI. In the four clinical studies, the mean number needed to treat to avoid one AKI event was 15 and the hospital's AKI cost avoidance was US\$906 with each DyeVert used.

Exhibit 1 – Cost savings associated with DyeVert System



Source: Bunney et al., 2019., Kutschman, R et al. 2019, Sattar, A et al. 2018, Briguori C, et al., 2020.

Research supports the approach

It has been shown that volume of contrast media administered and hydration status were two factors that could modify the development of CIN.¹⁶ Similarly, an analysis of 95,625 patients from the Blue Cross Blue Shield of Michigan Cardiovascular Consortium found that a 30% reduction in contrast dose would be expected to reduce the incidence of CIN by 12.5%.⁵ Another analysis showed that each incremental 75 ml of contrast used increased the risk of AKI by 42%.²⁰

Significant Opportunity

Market Size

Each year, ~7 million angiography procedures are performed in the US and Western Europe. Of these patients undergoing heart and lower limb procedures, 3.2 million are at risk of acquiring contrast-induced AKI due to risk factors including Stage 3-5 CKD, diabetes, and emergency heart (STEMI) procedures.^{2,14} With an average selling price of US\$350 per procedure, the US and Western European market size for DyeVert is US\$1.3bn.

No Direct Competition

Physicians use various preventative strategies to try to reduce the amount of contrast in angiography procedures including biplane imaging, intravascular ultrasound, and using smaller catheters. However, all of these have drawbacks.²¹ Studies show that there is still a large variability in the amount of contrast given to patients who are at risk for acquiring AKI.¹⁹ The DyeVert Systems is the only FDA-approved and CE-Marked device to reduce the amount of contrast dye used in angiography procedures. The imaging aspect is important. Cardiologists need clear pictures of the arteries to detect any pathology. Reducing the dye must not be at the cost of poorer imaging.

Clinical and Regulatory Support

The strength of the research studies demonstrating the relationship between the volume of dye used and incidence of AKI has seen the relevant regulatory and medical bodies adopt guidelines that recommend contrast dye reduction in at-risk patients.

United States

American College of Cardiology (ACC) and American Heart Association (AHA)

Joint guidelines from key medical societies relating to contrast dye-related kidney damage call for the reduction of contrast induced acute kidney injury (CI-AKI) through:

- the need to screen patients for risk of CI-AKI,
- ensuring proper hydration for all patients, and
- employing dye-minimisation strategies to avoid CI-AKI.

The American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions (ACC/AHA/SCAI) guidelines recommend:

- appropriately hydrating the patient pre-, intra-, and post-cardiac procedure
- minimising contrast volume in patients with chronic kidney disease (eGFR < 60 ml/min) including monitoring for contrast dosage in real-time and establishing contrast thresholds.

US Medicare Hospital Readmission Reduction Program

The Hospital Readmissions Reduction Program (HRRP) is a Medicare value-based purchasing program to encourage better care coordination and reduce avoidable readmissions. It aims to link payment to the quality of hospital care by reducing payments for excess readmissions. The program includes acute myocardial infarction (AMI) and coronary artery bypass graft (CABG) surgery for which coronary angiograms are commonly part of care.

Europe

UK National Institute for Health and Care Excellence (NICE)

The UK's NICE is responsible for developing guidelines of the use of health technologies in the UK National Health Service (NHS). Its economic analysis of the DyeVert™ Plus EZ system showed it had the potential to reduce healthcare costs improve quality of life and clinical outcomes for patients with Chronic Kidney Disease (CKD) stage 3–4 undergoing angiographic procedures. Base-case results indicate that the intervention leads to cost savings ~£435 per annum with £3,878 per patient over a lifetime and improved effectiveness (+ 0.028 QALYs).²² The overall long-term cost saving for the NHS was £19.7m for each annual cohort of patients, with 100% probability of being cost-effective and 100% probability of being cost saving to the UK healthcare system. The cost savings were mainly driven by a lower risk of subsequent diseases and the associated burden.

The European Urogenital Society

The European Society of Urogenital Radiology guidelines on contrast media also recommend the lowest dose of contrast medium consistent with a diagnostic result and to use of low or iso-osmolar contrast media.

Opportunity Not As Yet Fully Realised

Despite the clinical need and the strong regulatory and economic arguments to support OSP’s DyeVert device, OSP is yet to fully realise the clinical opportunity from a commercial perspective. Some 6 years following its initial market launch, OSP sales total in the low millions with ongoing losses. Review of its financial performance points to 3 areas – sales revenues, sales/marketing and R&D expenses.

Sales for 2019 represented of \$3.7m against sales and marketing costs of \$9m and R&D \$3m. To 2019, the company’s sales strategy has been to have a direct sales force in the US with some limited exposure to the EU.

Exhibit 2 – Abbreviated financial summary (FY14–FY19)

	FY14	FY15	FY016	FY17	FY018	FY19
\$m						
Sales	0.01	0.2	0.5	1.6	2.5	3.7
% change		-75%	217%	197%	56%	44%
Sales and Marketing expenses	1.2	1.7	3.8	7.1	10.0	10.7
% change		48%	125%	86%	40%	7%
% of Sales	165%	983%	697%	436%	393%	292%
R&D expense	3.0	2.9	3.5	3.2	3.6	3.1
% change		-3%	45%	52%	47%	54%
% of Sales	429%	1686%	639%	198%	143%	84%
Net Loss	9.7	12.2	11.8	14.3	17.5	18

Source: Osprey Medical.

Active Pipeline Brings Added Cost

In MST’s view, the modest market uptake reflects two key factors:

1. The marketing process is elongated and costly. It includes engagement of medical specialist advocates, regular medical conference attendance, highly skilled sales representatives and endorsement by healthcare payers. Commonly the engagement sales process can extend to over 6 months and beyond.
2. The strong and relatively rapid pipeline of new products over recent years has slowed commercialisation. While the pipeline of new products has brought significant clinical benefits, it has also hampered the commercial uptake. With each new generation of OSP’s pipeline to date, it has been necessary to re-engage with the different participants, both the regulatory and marketing/payer each time. The result for OSP has been higher R&D costs and lost sales momentum. The slower market penetration has impacted the fixed cost base of the sales force.

Lengthy multi-layered sales/marketing process

Coronary and peripheral angiograms and cardiac stenting are usually conducted in cardiac catheter laboratories (cath labs). In the US, OSP must garner the support of the clinicians who commonly account for ~8-10 cardiologists per cath lab. The initial awareness of a new product/technology is usually achieved through presentations at appropriate medical conferences/meetings and through studies in scientific publications.

To drive product awareness among the physician community, OSP develops support from key opinion leaders or advocates to present research studies at leading industry events and/or conduct clinical studies and publish the data in peer-reviewed journal articles. OSP’s sales team undertakes to provide further education over time to help establish the need and integration of the new technology into the clinicians’ laboratory’s treatment/diagnostic

protocols. Over 2019, the DyeVert system was presented at 10 scientific symposiums attended by >26,000 clinicians and their associates.

Once there is clinicians' support to use the device, OSP applies to hospital or laboratory management committees to have the device included in inventory. A cost-benefit analysis is needed to support the application through the buying committee. Once the new technology is available, integration into the clinics' practices occurs over time.

The product development pipeline and sales/marketing program, while critical to develop market uptake, have contributed to the slow uptake of OSP's devices. Each generation of product has required R&D time and cost as well as regulatory fees and approval processes. Re-education of OSP's users also stalls market penetration.

Ongoing evolution of OSP's product offering

OSP has an active development pipeline since its market debut. It has been shaped by technology updates and its customers, the cardiologists using the devices. While the pipeline has added improved clinical features, the launch of new products has hampered uptake.

Exhibit 3 – OSP product development timeline



Source: Osprey Medical

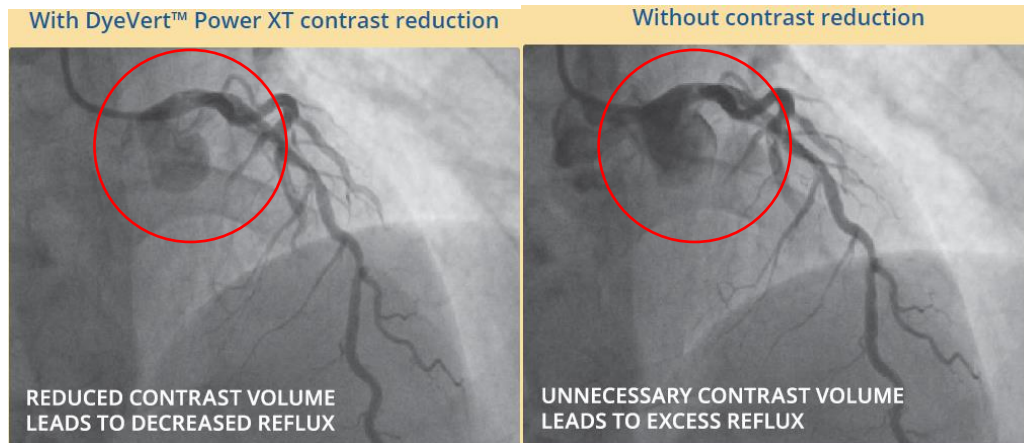
A pilot trial of OSP's initial technology, **CINCOR system**, showed it to be safe and effective in capturing and removing contrast dye as it exited the heart. Essentially, this system was a specialised catheter which would simultaneously block the artery and apply a vacuum to capture and remove the dye as it left the heart, thereby preventing the dye from traveling on to the kidneys. Ongoing development saw the access point changed from the jugular vein in the neck to a 'safer' site, the femoral vein in the groin. The pilot trial supported a Conformité Européenne (CE) Mark approval for the EU market in 2011, with market entry in 2012.

CINCOR underwent further development, evolving into **AVERT** with the ability to minimise the patient's exposure to contrast dye by reducing 'aortic reflux'. This term describes excess dye that overflows into the aorta when injecting into the target coronary artery. Rather than entering the target artery, refluxed dye travels from the aorta to the renal arteries, directly to the kidneys. However, contrast agents contain iodine which can be toxic to the kidneys and can lead to serious kidney damage.

The AVERT Plus contrast reduction/monitoring system added a disposable smart syringe and reusable LCD monitor to the AVERT. In addition to contrast savings, it also enabled the clinician to monitor and display the amount of dye

used versus the physician's inputted threshold volume. It was approved in the EU and Australia in 2012 and received FDA 510(k) clearance in late 2014. OSP initiated pilot commercialisation of the AVERT system and gained valuable feedback from early adopters on the utility of the device and learned the keys to market adoption. These early experiences led to the development of the DyeVert System which improved performance consistency and ease of use.

Exhibit 4 – Aortic reflux with and without the use of DyeVert Power XT



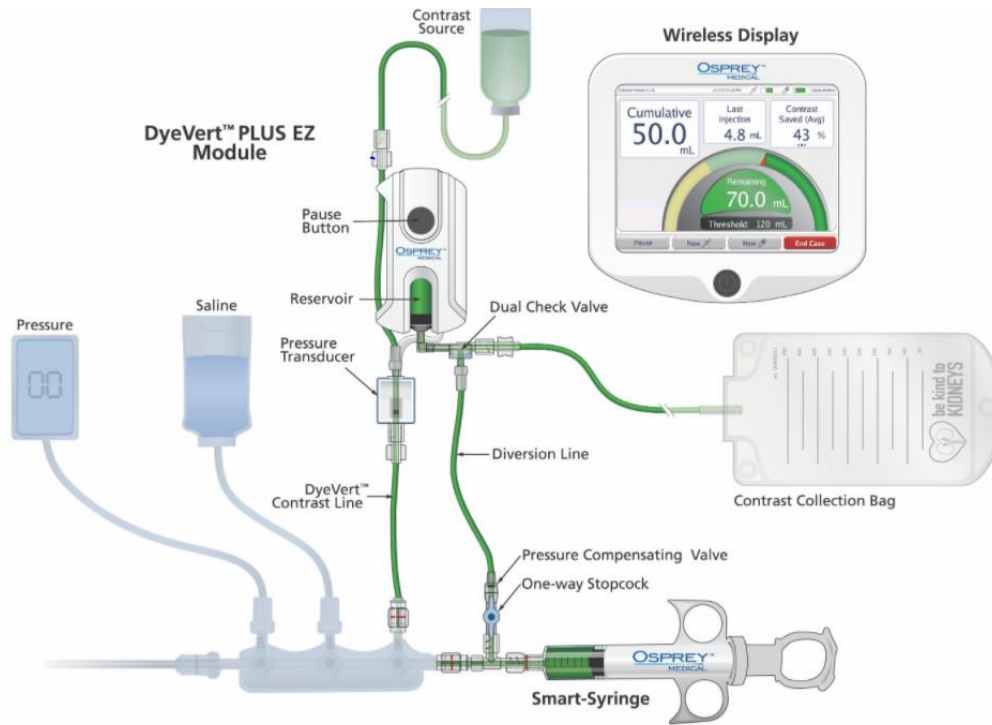
Source: Osprey Medical.

The **current generation DyeVert™ PLUS EZ system** transforms the capabilities of AVERT Plus into a compact, user-friendly device. The DyeVert PLUS EZ system, both FDA-approved and CE Marked, acts to divert a portion of the injected contrast, reducing aortic reflux so that the DyeVert can reduce the dye needed for the procedure without affecting image quality. Clinical studies have reported >40% average reduction in contrast dosage injected to the patient.¹

Together, the DyeVert™ PLUS EZ module, smart-syringe and monitor wirelessly communicate real-time contrast monitoring throughout each procedure to provide the clinician with ongoing feedback and an opportunity to adapt the procedure.

¹ Desch, S. et al. Impact of a novel contrast reduction system on contrast savings in coronary angiography – The DyeVert randomized controlled trial. *Int J Cardiol* (2018) <https://doi.org/10.1016/j.ijcard.2017.12.107>

Exhibit 5 – DyeVert PLUS EZ Module



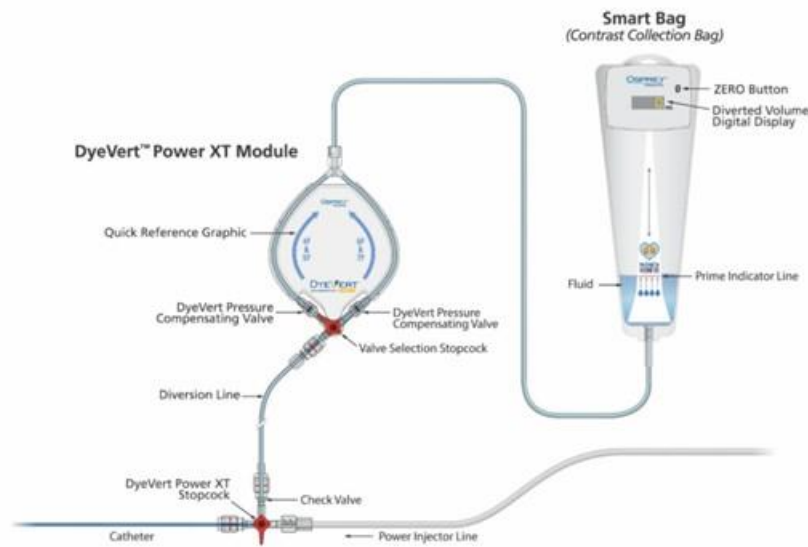
Source: Osprey Medical.

DyeVert™ Power XT has been developed for reducing contrast in angiographic procedures that utilise automated power injectors. This expands the market over that of DyeVert PLUS EZ alone, which addresses only manifold manual syringe procedures. Clinical results show that DyeVert™ Power XT incrementally reduces contrast dye by an average of 34%.³ Automated contrast media injectors control contrast dosage, record the amount used, speed injections to keep up with fast CT scanners, and warn of potential hazards, such as air embolisms or extravasations.

DyeVert PLUS EZ and DyeVert Power XT effectively cover the two standard cardiac angiogram versions: manual syringes and automated injectors. DyeVert PLUS EZ is compatible with manual injections which comprise 75% of coronary angiography procedures in the US. DyeVert Power XT has CE approval for Europe and is expected to receive FDA approval in Q1CY21. Approximately 25% of US hospitals use automated power injectors for coronary angiography procedures.

OSP’s second product, **DyeTect**, was approved by the FDA and Europe’s EMA in late 2017. DyeTect enables real-time dye threshold monitoring and accurate accounting of total dye dose to the patient for all dye-based heart procedures. To date, its contribution to sales revenues and earnings has not been material.

Exhibit 6 – OSP’s DyeVert™ Power XT model



Source: Osprey Medical

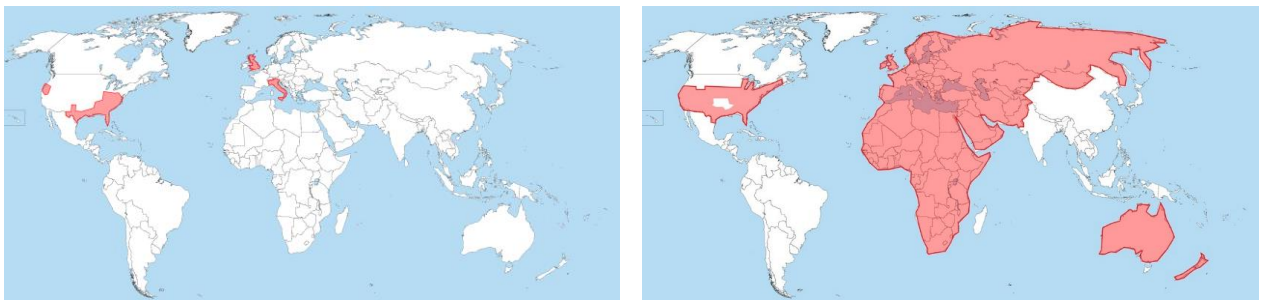
Coming of Age: Commercialisation Strategy to Reach Full Opportunity

The DyeVert evolution represents the development program reaching maturity. The offering is now fully oriented to meeting clinicians’ needs and maximum patient benefit with only incremental changes expected going forward.

One of the resulting benefits for OSP is that it is positioned to seek partnerships to extend its commercial reach. To date it has secured an ex-US agreement with leading industry player GE Healthcare and appointed its first independent sales agent (ISA), BioCore, as part of its strategy to expand its US coverage. It plans to appoint further ISA companies to cover the key US regions.

As illustrated below, OSP’s markets have expanded exponentially over the past 12 months.

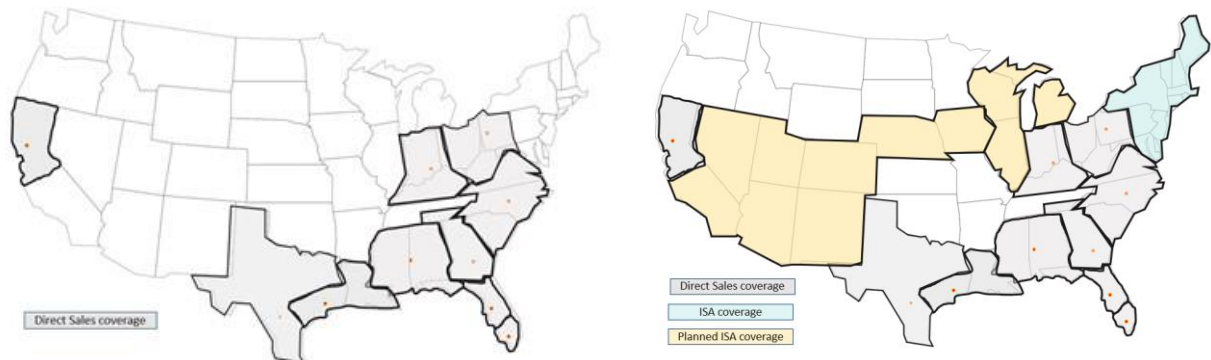
Exhibit 7 – World coverage: June 2020 (left), Q1 2021 (right)



Source: Osprey Medical

US Market Strategy

Exhibit 8 – US sales coverage: 2020 (left), Q1 2021 (right)



Source: Osprey Medical

Direct sales force

In the key market of the US, OSP has operated its own sales force. The focus has been on territories with large populations of patients with CKD who are at high risk of developing kidney damage. In 2020 OSP's direct sales force covered 18 states with a team of 15 full-time employees focused on protecting poor kidney function patients from AKI and on lowering hospital costs.

Indirect sales force

In December 2020, OSP announced the appointment of BioCore Inc., an independent sales group. The aim is to expand market coverage in a cost-effective way. Under the agreement, BioCore's sales reps will cover 8 US states, adding to those already covered by OSP's sales force. The representatives promote cardiac surgery, electrophysiology and cath lab products and therefore present expertise in the relevant areas of therapy and familiarity with the existing clinicians. The OSP direct sales team will be available to attend more advanced meetings to ensure there is a sufficient level of expertise. OSP will look to appoint more independent sales forces to expand its coverage.

GPOs

In 2019, OSP had five national GPO agreements, including Premier, one of the largest GPOs in the US, with 4,000 hospitals covered. Effectively, the agreements cover medical facilities that account for ~50% of the angiogram procedures. GPOs are multi-hospital systems that aggregate the purchasing volumes of their members to negotiate favourable goods and service agreements.

While some margin is surrendered, suppliers look to higher volumes. While the GPOs do not actively market the products on behalf of the suppliers, they offer significant cost advantage and facilitate more expeditious supply. Commonly the time to negotiate a new agreement is ~6 months. This compares to an average time of ~4 months for a GPO-covered hospital agreement.

Premier has an interest in the impact of AKI on patient outcomes and hospital costs. It engaged its own analytics team to better understand the impact of the disease. The analysis, published at the American College of Cardiology's annual meeting, showed AKI in patients receiving coronary stents was a rising problem (18% AKI rate in 2012 rising to 32% in 2017) leading to poor patient outcomes and a \$1.6 billion spend for member hospitals. Premier awarded OSP with Breakthrough Technology designation for its DyeVert portfolio of products that can improve patient care and reduce hospital costs.

In 2019, DyeVert unit sales to GPO hospitals accounted for 62% of total revenues (vs. 45% in 2018). The average selling price of DyeVert in GPO hospitals was stable at \$350 throughout 2019, in line with the GPO contract pricing.

EU and Rest of World Market Strategy

OSP terminated its two distribution agreements in Europe after negotiating a four-year ROW exclusive distribution agreement with GE, which was announced in July 2020. The agreement encompasses all the key markets of the EU, Asia and Africa. GE also has right of first refusal to distribute and promote any new products introduced by OSP. The agreement includes increasing minimum purchase levels with agreed gross margin returns for OSP and annual minimum sales volumes and a fixed transfer price over the term of the agreement.

The agreement commenced in H2CY20, and effectively adds 120+ effective full-time employees and is expected to add 20% sales in CY21 to grow to 40%+ of expected revenues in CY24. GE is the largest global player in contrast media and molecular imaging agents. Its customer base in 140 countries includes North America, Europe, the Pacific Basin, the Americas, and the Middle East & Africa. The agreement does not include North America, which remains under OSP and its US-based partnerships.

In November 2020, OSP announced a three-year agreement with Australian-owned medical distribution company Regional Health Care Group Pty Ltd (RHCG) which will see RHCG exclusively distribute OSP's products across Australia and New Zealand. RHCG is a highly successful medical distribution company with a track record of more than 40 years, including extensive experience in supplying medical equipment, contrast media and medical consumables to the radiology and cardiology imaging sector across Australia. Marketing programs have commenced in Australia.

Valuation, Risks and Sensitivities

MST valuation of 3.4 cents per CDI is derived from a 12 month forward discounted cash flow. The WACC calculation assumes an equity beta of 1.50 risk-free rate of 4.0%, a terminal growth rate of 2.5%, an expected market return of 10%, giving us a WACC of 13.0%.

The forecast CY20 fall in sales to US\$1.6m from US\$3.7m in FY19, reflects the impact of COVID in its US market. The forecast assumes sales momentum will return from CY21. The key drivers of growth going forward are the GE contract for ex US markets and US independent sales forces which will significantly increase OSP's US market reach.

The nature of the agreements impacts the revenue/costs structure going forward. The GE model is based on a transfer pricing arrangement. The lower revenue per unit will mute the margin expansion from volume efficiencies. As the relative contribution of the GE sales grows, the gains in gross margin from volume efficiencies will be masked by the relative lower sales contribution from the GE sales.

Sales and marketing expenses, a key expense item, will be impacted by the higher sales costs from the US ISA agents agreements. Conversely, under the transfer pricing model, sales and marketing costs will not be attributed to the GE sales.

Overall, the model assumes that the higher volume sales will expand the gross margins from an underlying ~50% to ~60+%. Total costs of ~\$20m recorded for FY19 are forecast to fall in response changes in OSP's direct sales force over CY20 and the GE model for ex US markets. OSP has tax losses which may qualify to offset future tax charges.

There is execution risk associated with achieving the sales growth and COGS efficiencies to expand the gross margin and meet the earnings forecasts. Additional funding maybe required over FY22/FY23. Risk arises from the company's exposure to COVID and its ability to generate the sales forecast and reduce the overheads.

Exhibit 9 – Abbreviated financial forecast summary

DCF Operating Cash Flows										
\$m	FY21E	FY22E	FY23E	FY24E	FY25E	FY26E	FY27E	FY28E	FY29E	FY30E
EBITA	(10.1)	(4.8)	0.0	1.9	4.3	7.8	12.3	17.6	23.4	29.5
Forecast cash tax	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	(0.6)	(8.9)
Depreciation	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Change in Working Capital	(0.5)	(0.5)	(0.6)	(0.6)	(0.7)	(0.7)	(0.8)	(0.9)	(1.0)	(1.1)
Change in Equity	12.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Acquisitions / Other	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Capital Expenditure	(0.3)	(0.3)	(0.3)	(0.3)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)	(0.4)
Standard Free Cashflow	1.4	(5.3)	(0.6)	1.2	3.6	7.0	11.4	16.6	21.7	19.4
FCF Timing Factor	1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0
Discount Factor	1.1	1.3	1.4	1.6	1.9	2.1	2.4	2.7	3.0	3.4
Discounted FCF	1.3	(4.2)	(0.4)	0.8	1.9	3.4	4.8	6.2	7.2	5.7
Valuation										
Explicit Cashflows (10 Years)	27									
Terminal Value	54									
Total Firm Value	80									
Plus Cash (Net debt)	4									
Option exercise cash	10									
Total Equity Claims	95									
Diluted CDs end of FY21	3,618									
Per CDI Value (US\$)	\$0.026									

Income Statement Analysis

December Year End	US\$m	FY18	FY19	FY20E	FY21E	FY22E	FY23E
Sales revenue		2.5	3.7	1.6	5.7	13.2	21.4
Other Income (excluding one offs)		0.0	0.0	0.0	0.0	0.0	0.0
Total Income		2.5	3.7	1.6	5.7	13.2	21.4
COGS		(1.4)	(1.8)	(1.1)	(3.2)	(5.3)	(8.3)
Gross margin		1.1	1.9	0.5	2.5	7.9	13.1
Corporate costs		(18.7)	(19.9)	(16.2)	(15.8)	(18.0)	(21.4)
EBITDA		(17.6)	(18.0)	(14.6)	(10.1)	(4.8)	0.0
Depreciation		(0.3)	(0.3)	(0.3)	0.0	0.0	0.0
EBITA		(17.8)	(18.2)	(14.9)	(10.1)	(4.8)	0.0
Amortisation of intangibles		(0.0)	(0.0)	0.0	0.0	0.0	0.0
EBIT		(17.9)	(18.2)	(14.9)	(10.1)	(4.8)	0.0
Interest income		0.3	0.2	0.0	0.0	0.0	0.0
Interest expense		0.0	0.0	0.0	(0.1)	(0.1)	(0.1)
Net Interest income / (expense)		0.3	0.2	0.0	(0.0)	(0.0)	(0.1)
PBT		(17.5)	(18.1)	(14.9)	(10.1)	(4.9)	(0.0)
Taxation		0.0	0.0	0.0	0.0	0.0	0.0
NPAT		(17.5)	(18.1)	(14.9)	(10.1)	(4.9)	(0.0)
Minority interests		0.0	0.0	0.0	0.0	0.0	0.0
NPAT		(17.5)	(18.1)	(14.9)	(10.1)	(4.9)	(0.0)

Balance Sheet Analysis

A\$m	FY18	FY19	FY20E	FY21E	FY22E	FY23E
Cash and Deposits	25.3	8.3	4.3	5.7	0.4	0.1
Receivables	0.4	0.5	0.2	0.7	1.7	2.7
Inventories	0.8	0.9	1.0	3.6	8.2	13.4
Other Current Assets	0.2	0.1	0.1	0.1	0.1	0.1
Total Current Assets	26.7	9.8	5.6	10.1	10.3	16.2
PPE	0.7	0.6	0.6	0.6	0.6	0.6
Receivables	0.0	0.0	0.0	0.0	0.0	0.0
Goodwill	0.0	0.0	0.0	0.0	0.0	0.0
Intangibles	0.0	0.0	0.0	0.0	0.0	0.0
Other / Leased Assets	0.1	0.5	0.4	0.4	0.4	0.4
Total Non-Current Assets	0.8	1.0	1.0	1.0	1.0	1.0
Total Assets	27.5	10.8	6.6	11.1	11.3	17.2
Interest Bearing Debt	0.0	0.0	0.0	0.0	0.0	0.0
Payables	0.9	1.1	0.5	1.7	3.9	6.4
Employee Benefits	1.0	1.1	0.9	0.9	1.0	1.0
Provisions	0.0	0.0	0.0	0.0	0.0	0.0
Other Short Term Liabilities	0.0	0.1	0.1	0.1	0.1	0.1
Total Current Liabilities	1.9	2.4	1.5	2.8	5.0	7.5
Interest Bearing Debt	0.0	0.0	1.3	1.3	1.3	1.6
Deferred Tax Liabilities	0.0	0.0	0.0	0.0	0.0	0.0
Other LT liabilities	0.1	0.4	0.4	0.4	0.4	0.4
Total Non Current Liabilities	0.1	0.4	1.7	1.7	1.7	2.0
Total Liabilities	2.0	2.7	3.2	4.5	6.7	9.5
Shareholders Funds	122.3	122.9	132.6	144.6	144.6	144.6
Retained Earnings	(96.8)	(114.8)	(129.4)	(139.5)	(144.4)	(144.4)
Reserves	0.0	0.0	0.1	1.5	4.3	7.5
Other	0.0	0.0	0.0	0.0	0.0	0.0
Total Equity	25.5	8.1	3.4	6.6	4.6	7.7

Source: Osprey Medical .MST Estimates

Board and Management

Management

Mike McCormick, President & CEO

Mike has more than 30 years of experience in the medical device industry and President level experience with both public and private medical device companies. Prior to Osprey Medical, he was President/CEO of Anulex Technologies, Inc., focused on supporting the healing of spinal soft tissues; President of Centerpulse Spine-Tech and was involved in the successful sale of Centerpulse Inc. to Zimmer in 2003 for US\$3.2 billion. Mike also spent 10 years in sales and sales leadership positions with Boston Scientific's Cardiovascular Division (SCIMED) and Baxter Healthcare. Mike received a BBA from the University of Texas at Austin and is an active board member at Formae, Inc.

Vic Fabano, Vice President of Operations and IT

Vic has more than 25 years' experience in the medical device industry, holding executive positions in Operations, Quality, and Product Development for more than 15 years. His expertise is scale-up of FDA compliant operations infrastructure focused on cost, quality and delivery. Prior to Osprey Medical, Vic was Vice President of Operations and Quality for Anulex Technologies, and served in a similar capacity for several start-ups to midsize medical device firms in the Twin Cities. Vic has a bachelor's degree in Mechanical Engineering from the University of North Dakota.

Melanie Hess, Vice President of Regulatory, Compliance, and Quality

Melanie has over 20 years of medical industry experience specializing in regulatory strategy, compliance, and global regulatory affairs. Prior to Osprey Medical, she led Regulatory Affairs for Women's Health at American Medical Systems, Endo Pharmaceutical (AMS), and prior held increasingly responsible positions at St. Jude Medical and Smiths Medical. She also spent 8 years as a practicing intensive/critical care licensed nurse (R.N.) in local Level I Trauma centers. Melanie holds a BSN from the University of Minnesota and an MBA from the University of Phoenix.

Sarah Runde, MSN, FNP, Senior Director, Clinical Affairs

Sarah is a nurse practitioner with nearly 25 years of clinical research experience in hospital, outpatient, and industry settings supporting evidence development for pharmaceutical and medical device products. She spent 15 years at Medtronic in positions of increasing strategic and operational leadership including development and management of high-performing global teams. Prior to joining Osprey Medical, Sarah managed a global team responsible for execution of brain modulation clinical strategies across multiple therapy areas including epilepsy, Parkinson's Disease, dystonia, depression, and OCD. Sarah holds a B.A. degree (dual biology and psychology) from Luther College in addition to a B.S.N. degree, M.S.N. degree, and Family Nurse Practitioner Certificate from Case Western Reserve University.

Rodney Houfburg, Vice President of Research & Development

Rod has 25 years medical device experience in R&D. He is the inventor or co-inventor on 33 issued US patents. Before Osprey Medical, Rod was Vice President of Research and Development for Anulex Technologies, Director of Product Development for Centerpulse Spine-Tech (Zimmer Spine) and developed orthopedic products at Wright Medical Technology. Prior to medical devices, Rod developed smart weapons at Alliant Techsystems. He has a Bachelor of Mechanical Engineering from the University of Minnesota.

Nancy Ness, Vice President of Finance

Nancy has more than 25 years' experience and is the chief financial officer for several medical device companies, including Osprey Medical. She brings financial and fundraising expertise to over 28 medical device start-up companies in Minnesota, New York, and California. Nancy is a board member and founder of Vatrix Medical, and has provided financial services to Anulex Technologies, Northwest Airlines (Delta), and Home Styles Publishing and Marketing. She earned a BA in Accounting and Business Administration from the University of St. Thomas and holds a Certified Public Accountant license.

Doug Schoenberg, Vice President Marketing, Education & Reimbursement

Doug has 20 years of experience in marketing, reimbursement, and executive roles in Cardiology, Cardiac Surgery, and Spine. Prior to Osprey Medical, he held marketing management positions at Anulex Technologies, St. Jude Medical, Zimmer Spine, and Schneider (now part of Boston Scientific). From start-up to broad commercial sales environments, Doug has built scalable business models from product concept through successful marketing and sales execution. He holds an MBA in Marketing from the University of Minnesota and a B.B.A from St. Cloud State University.

Board of Directors

John Erb, Non-Executive Chairman

John joined the board of the Company as an independent director and non-executive Chairman in June 2007. John has over 40 years of experience in the medical device industry. He is currently Chairman of the Board and Chief Executive Officer of CHF Solutions, Inc., a manufacturer of medical devices for the heart failure market. John previously served as Chairman of the Board for Vascular Solutions, Inc., manufacturer of medical devices for the cardiology and interventional radiology markets, which was acquired in 2017 by Teleflex, Inc. for US\$1 billion. He has held numerous board positions, including CryoCath Technologies, Inc., acquired by Medtronic for US\$350 million in 2008; and SenoRx, Inc., acquired by C.R. Bard for US\$250 million in 2010. John has a bachelor's degree in Business Administration from California State University, Fullerton.

Andy Jane, Non-Executive Director

Andy has more than 20 years of experience in the biomedical and IT industries. He is a Managing Director with Talu Ventures in Brisbane, Australia, with a portfolio of investments formerly managed by CM Capital Investments. Andy is a Board member of Piedmont Animal Health; Advent Pharmaceuticals Pty; Altiris Pharmaceuticals Inc.; and Piedmont Pharmaceuticals, Inc. He has a BSc Hons degree in Physics from the University of St Andrews in Scotland; a Master of Science degree in Instrumentation from the University of Manchester; a Diploma of Financial Services (Financial Markets) from AFMA; and a post-grad Certificate in Science Media & Journalism from the University of Technology in Sydney.

Sandra Lesenfants, Non-Executive Director

Sandra currently serves as the Vice President & General Manager of endoVenous business in the Medtronic Cardiac & Vascular Group. In her role, she is responsible for leading the development and global marketing of meaningful innovations and solutions to address chronic venous insufficiency, deep venous disease, and vascular embolization. Sandra has broad commercial strategy experience and global business management skills from the vascular businesses at Medtronic, Covidien, EV3, and Siemens Healthcare. She has led several key integrations including the acquisition of Sapheon and its VenaSeal closure system, the integration of endoVenous business from Covidien's Vascular Therapy business into Medtronic, and the integration of the embolization sales team from Medtronic's Neurovascular division into endoVenous. Sandra is on the Board of Directors of The American Venous Forum Foundation. She has a biomedical computer engineering degree from the University of Technology of Compiègne Engineering Institute in France.

Neville Mitchell, Non-Executive Director

Neville joined the board of the Company as an independent non-executive director in July 2012 and is the Chairman of the Audit and Risk Committee. Neville was CFO and Company Secretary of Cochlear Limited from 1995 to 2017. He is a non-executive Director of Sonic Healthcare (since 2108), Fisher and Paykel Healthcare (since 2018) and Q'Biotics (since 2017). He is a member of the Australian Board of Taxation and a director of the South East Sydney Local Health District Board. Previously he served on the New South Wales Medical Devices Fund, was Chairman of the Group of 100 and Chairman Standing Committee (Accounting and Auditing) for ASIC. Neville has a Bachelor of Commerce Degree and is a member of Chartered Accountants Australia and New Zealand.

Chris Nave, Ph.D., Non-Executive Director

Chris is a founding partner of Brandon Capital Partners and Chief Executive Officer of the Medical Research Commercialisation Fund. Brandon Capital is a leading Australian life science investment firm with over \$500M in assets currently under management. Chris was previously Director of Commercialisation at the Baker IDI Heart and Diabetes Institute, Melbourne, Australia, where he led the commercialization of technologies developed at the Baker and Alfred Hospital. Chris was also Manager of the Biotechnology Team at Melbourne Ventures, the commercialisation company of the University of Melbourne. In 2014, Chris was awarded the Australian Biotechnology Johnson & Johnson Industry Leadership Award, for his contribution to the industry. Chris is currently a Director of Global Kinetics Corporation, PolyActiva, OccuRx Therapeutics, QueOncology and Athena Medicines. Chris has a first-class Honours degree in Science and a Ph.D. in Endocrinology and Physiology from the University of Melbourne and he has completed the Private Equity and Venture Capital Program.

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