BELL POTTER

31 January 2017

**Speculative**

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


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# Osprey Medical

## Strong Momentum Into 2017

**Recommendation**
Buy (unchanged)
**Price**
$0.44
**Valuation**
$0.55 (previously $0.53)
**Risk**
Speculative

**GICS Sector**

**Healthcare Equipment and Services**

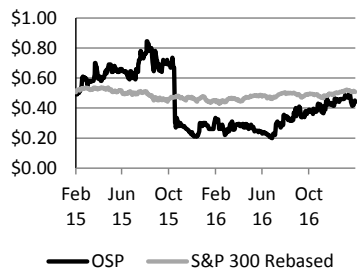
| Expected Return | |
|---|---|
| Capital growth | **25.0%** |
| Dividend yield | **0.0%** |
| Total expected return | **25.0%** |

| Company Data & Ratios | |
|---|---|
| Enterprise value | **$89.4m** |
| Market cap | **$113.4m** |
| Issued capital | **257.7m** |
| Free float | **100%** |
| Avg. daily val. (52wk) | **$59,000** |
| 12 month price range | **$0.19 - $0.51** |

**Price Performance**

| | (1m) | (3m) | (12m) |
|---|---|---|---|
| Price (A$) | 0.46 | 0.43 | 0.26 |
| Absolute (%) | -4.35 | 2.33 | 69.23 |
| Rel market (%) | -3.27 | -2.33 | 55.59 |

**Absolute Price**




SOURCE: IRESS

## Key Points from December Quarterly Update

The company achieved 43% unit sales growth across all territories for the quarter. Unit sales in the pilot sales territory of San Antonio continue to expand and there are now 15 sales reps in the field in the US, up from 9 at the end of September.

San Antonio achieved its maiden quarter of profitability following two years of market development. Unit sales in the territory exceed the breakeven point of 75 units per month for the first time.

Also during the December quarter, the number of hospital buyers expanded by 22% to 45. There is a pipeline of 40 additional hospitals across the new sales territories currently evaluating the Dyvert system.

The company does not anticipate any material impact from the change of Government in the US. While it appears the Affordable Care Act (Obama Care) will be rolled back, the reimbursement stick imposed by Medicare and private payers on hospitals with below average care ratings will continue. This is a major positive for the company as adoption rates continue to increase as hospital operators seek methods to minimise poor patient outcomes.

## Maintain Buy Rating

There are no significant changes to our earnings forecast. Valuation is amended from $0.53 to $0.55 due to small changes in the DCF model. We maintain our Buy rating. The number of hospitals using DyeVert continues to expand each quarter and it is reasonable to expect this will continue to grow. We conclude that the execution of the sales plan continues to progress well.

**Earnings Forecast**

| December Year End US$m | FY15 | FY16e | FY17e | FY18e |
|---|---|---|---|---|
| Revenues | 0.2 | 0.6 | 4.2 | 13.3 |
| EBITDA $m | -12.2 | -11.0 | -10.3 | -4.9 |
| NPAT (underlying) $m | -12.2 | -10.6 | -9.9 | -4.5 |
| NPAT (reported) $m | -12.2 | -10.6 | -9.9 | -4.5 |
| EPS underlying (cps) | -8.3 | -4.9 | -3.9 | -1.7 |
| EPS growth % | 19% | -42% | -20% | -55% |
| PER (x) | -5.3 | -9.1 | -11.4 | -25.2 |
| FCF yield (%) | -17% | -9% | -9% | -4% |
| EV/EBITDA (x) | -7.3 | -8.1 | -8.6 | -18.3 |
| Dividend (cps) | - | - | - | - |
| Franking | 0% | 0% | 0% | 0% |
| Yield % | 0.0% | 0.0% | 0.0% | 0.0% |
| ROE % | 0.0% | -50.4% | -86.7% | -66.0% |

SOURCE: BELL POTTER SECURITIES ESTIMATES

# Hospital Buyers Grow by 22%

## Summary Financial Results – 4Q16

The key points from the 4Q16 cash flow statement and sales commentary were as follows:

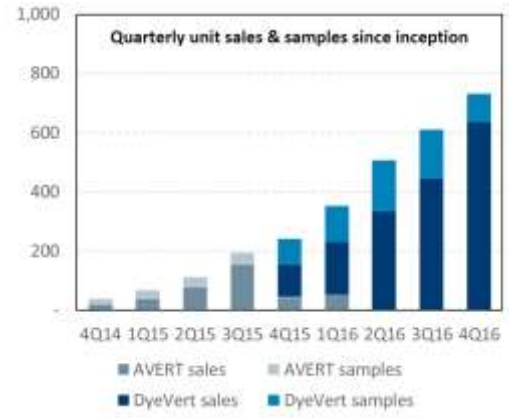
- Units sales growth of 43% vs 3Q16. The company sold 636 DyeVert units in the quarter relative to 446 in prior quarter. 2H16 unit sales grew by 86%.
- We continue to expect exponential revenue growth in FY17 driven by the expanded sales force now in place. Excluding the pilot sales territory of San Antonio, units sales in other 14 territories were 400 units in total or an average of 28 units per territory for the quarter. This equates to less than 10 units per month per territory.
- Conversely, the single sales rep in the San Antonio sold 236 units or the quarter or 79 units per month.

Our forecast for FY17 stands at 12,000 units which we derive from a bottom up methodology. The key assumptions are:

- An average of 20 reps in the field across the US. Currently there are 15 reps with the company on track to expand to 20 reps by the end of 1Q17.
- An average of 50 units per rep per month at US$350 per unit. The average of 50 units is across the year and we expect the result will be heavily skewed to 2H17.

We believe the path to profitability for the 19 new reps will be significantly ahead of the pilot market in San Antonio for the key reason that Dyvert is now second generation and there is significant clinical evidence supporting its use relative to when launched in San Antonio.

**Figure 1 - Quarterly Unit Sales and Samples**




SOURCE: COMPANY DATA

**Figure 2 – Quarterly Unit Sales History**

| | Q116 | Q216 | Q316 | Q416 | Total |
|---|---|---|---|---|---|
| Unit sales | 245 | 334 | 446 | 636 | 1,661 |
| Revenues US$'000 | 87 | 119 | 156 | 223 | 585 |
| Average selling price US$ | 355 | 356 | 349 | 351 | 352 |
| | | | | | |
| Puchasing hospitals | | 29 | 39 | 45 | |
| Average per hospital | | 12 | 11 | 14 | |

SOURCE: COMPANY DATA

- Free samples are provided to new hospitals trialling the product. The volume of samples issued in the quarter continues to be a strong proxy for the subsequent unit sales growth. 40 new hospitals (across all territories) are in the evaluation to purchase cycle. This is the same number of hospitals as reported in the previous quarter, however, there is a 25% churn in this statistic. Historically 85% of hospitals who sample the product become customers.
- 45 hospitals acquired product in 4Q16 – up from 39 in the previous quarter. Average unit sales per hospital is increasing which implies traction levels are improving – consistent with the experience in San Antonio.

OSP achieved 1,661 unit sales for the year which was below our target of 1,800, nevertheless the momentum going into calendar 2017 is accelerating.

- Cash receipts from customers were US$510K for the year. The company will report total revenues of US$585K for FY16.
- The cash outflow from operating expenses in the quarter was US$2.7m which equates to an annualised rate of US$10.8m. In FY17 we have allowed for A$13.7m in operating expenses. The FY17 estimate for operating expenses may need to increase modestly, however we await the full year result before considering any amendment to earnings.
- Closing cash was US$21.8m. The net cash burn for the quarter was US$2.6m.

**DYEVERT PLUS**

DyeVert Plus is the latest release product from the company. Its key value add is real time monitoring against a pre-set limit for dye use. The FDA is expected to grant approval in 1Q17.

## Valuation and Recommendation

There are no significant changes to earnings forecasts. Valuation is amended from $0.53 to $0.55 and we retain our Buy recommendation.

The valuation continues to be based on a Discounted Cash Flow model.

# Key Risk Areas

The clinical trial(s) which led to the approval of the first generation AVERT system and subsequent additions are now completed. Although these trials were ultimately not able to prove a reduction in CIN events, the claims for use of the product remain strong.

**Market Adoption Risk**

To achieve the sales revenue objectives, patients, physicians, hospitals and payers must accept the company's products, specifically the DyeVert™ system, for routine use. Regulatory approvals of the company's products, including US FDA approval, does not guarantee market adoption. Acceptance of the company's products in Europe and the US will be dependent on numerous factors, including but not necessarily limited to, market perception of the risk of CIN, risk benefit and cost-benefit analysis of the use of the company's products and reimbursement.

**Technical Risk**

The reasons for CIN are not fully understood by the medical community and are potentially multi-factorial and variable for each patient based on their health history and disease state. Given this patient variability there is no guarantee that minimising the amount of dye used will reduce the incidence of CIN.

**Intellectual Property Risk**

The company relies on its ability to obtain and maintain patent protection of products such as the DyeVert™ System. The company's patent portfolio comprises 8 issued US patents, 15 pending US patents, and 10 international patents. There are also National Stage Applications in the EU, Japan and Australia.

**Manufacturing and Product Quality Risk**

Osprey' products must also meet the regulatory requirements which are subject to continual review including inspections by regulatory authorities including the US FDA. Failure by the company or its suppliers to continuously comply with applicable regulatory requirements or failure to take satisfactory corrective action in response to adverse inspection, could result in enforcement actions, including a public warning letter, a shutdown of, or restrictions on, its manufacturing operations, delays in approving or clearing products, refusal to permit the import or export of its products or other enforcement action.

# About Osprey Medical

Osprey Medical is a US based company focused on the development and commercialisation of its proprietary DyeVert System. DyeVert aims to reduce the level of contrast used in certain diagnostic procedures involving the heart. Contrast Induced Nephropathy (CIN) is a serious medical condition related to kidney failure and is a side effect following use of contrast (dye) in angioplasty/cardiac stenting procedures.

Approximately 25% of patients undergoing angioplasty or cardiac stenting are at high risk of a CIN event due to their pre-existing kidney disease.

It is estimated there are up to 1.6m procedures (amongst high risk patients) conducted in the US each year that may benefit from the use of this technology. The DyeVert system has multiple measures aimed at minimising the volume of dye used, which should help reduce the number of CIN events in at risk patients.

Extensive clinical trials have now been completed in Australia, Europe and the US resulting in regulatory approvals in each of these jurisdictions.

In the US Osprey has its own dedicated sales force and does not use distributors and neither does the sales force sell any other products. It commenced marketing of the predecessor to DyeVert in 2014 with a single sales rep in Texas. Since then, it has consistently grown units sold and sampled. We expect this trend will continue as the company intends to expand the number of sales reps. In addition the company has added clinical specialists to assist the interventional cardiologist and nursing staff in their initial use of the system and training as required.

The conversion rate of hospitals upgrading from DyeVert samples to initial product orders remains high at approximately 85%. As the volume of samples expands, it is logical to assume commercial orders will follow.

There are four key drivers for physicians and hospitals to adopt the technology:

- Clinical trials proved there is up to 46% reduction in dye usage when the system is used as compared to when not used. The saving is highest in patients requiring multiple stents. Key opinion leaders in the US consistently advocate using less dye in order to reduce the risk of CIN events;
- Sub group analysis from the Avert trial showed a 49.5% reduction in the rate of CIN events in patients with grade 3 chronic kidney disease;
- Patients suffering a CIN event normally require additional hospitalisation for up to four days at a cost of up to $10K per day to hospitals with little or no incremental payer reimbursement; and
- Medicare/Medicaid payments to hospitals are at risk if the rate of unplanned readmission for Medicare patients exceeds the national average. Targeted re-admission includes heart failure and heart attack. Any patient admitted with chest pain is likely to meet this criteria. The penalties are severe and include a 3% revenue penalty on ALL Medicare payments to the effected hospital.

The company has invested approximately US$50m in the development of the technology to this point where it is now approved in major markets and generating revenues in the US. The company expects to commence a roll out in Europe in 2018. We expect the company will become breakeven by FY19 when revenues are expected to exceed US$20m.

# Osprey Medical
as at 31 January 2017

| | |
|---|---|
| Recommendation | Buy, Speculative |
| Price | $0.44 |
| Valuation | $0.55 |

## Table 1 - Financial summary

| Profit & Loss (US$m) | FY15 | FY16e | FY17e | FY18e | FY19e |
|---|---|---|---|---|---|
| **Year Ending December** | | | | | |
| **Device unit sales** | 430 | 1,661 | 12,000 | 39,000 | 84,000 |
| Net revenue from product sales | 0.2 | 0.6 | 4.2 | 13.3 | 27.2 |
| **COGS** | -0.4 | -0.3 | -0.8 | -2.7 | -5.4 |
| **Gross profit** | -0.2 | 0.3 | 3.4 | 10.6 | 21.7 |
| **GP margin** | 0% | 50% | 80% | 80% | 80% |
| R&D incentive/Upfront receipts | - | - | - | - | - |
| **Total revenues** | **0.2** | **0.6** | **4.2** | **13.3** | **27.2** |
| | | | | | |
| **Other expenses** | **-12.0** | **-11.3** | **-13.7** | **-15.5** | **-17.6** |
| **EBITDA** | **-12.2** | **-11.0** | **-10.3** | **-4.9** | **4.2** |
| D&A | 0.0 | -0.1 | -0.1 | -0.1 | -0.1 |
| **EBIT** | -12.2 | -11.1 | -10.4 | -5.0 | 4.1 |
| | | | | | |
| Sundry income | 0.1 | 0.5 | 0.5 | 0.5 | 0.5 |
| Pre tax profit | -12.2 | -10.6 | -9.9 | -4.5 | 4.6 |
| Tax expense | - | - | - | - | - |
| **NPAT- normalised** | -12.2 | -10.6 | -9.9 | -4.5 | 4.6 |
| Net abnormal items | - | - | - | - | - |
| **Reported NPAT** | -12.2 | -10.6 | -9.9 | -4.5 | 4.6 |

| Cashflow (US$m) | FY15 | FY16e | FY17e | FY18e | FY19e |
|---|---|---|---|---|---|
| Gross cashflow | -11.6 | -11.0 | -10.8 | -4.9 | 4.7 |
| Net interest | 0.3 | 0.5 | 0.5 | 0.5 | 0.5 |
| Tax paid | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Operating cash flow** | -11.4 | -10.5 | -10.3 | -4.4 | 5.2 |
| Maintenance capex | -0.1 | -0.2 | -0.2 | -0.2 | -0.2 |
| Capitalised clinical trial spend | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Free cash flow** | -11.5 | -10.7 | -10.5 | -4.6 | 5.0 |
| Business acquistions | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Proceeds from issuance | 11.9 | 21.0 | 0.0 | 0.0 | 0.0 |
| Movement in investments | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Dividends paid | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Change in cash held** | 0.4 | 10.3 | (10.5) | (4.6) | 5.0 |
| Cash at beginning of period | 11.3 | 11.8 | 22.0 | 11.6 | 7.0 |
| **Cash at year end** | 11.8 | 22.0 | 11.6 | 7.0 | 12.0 |

| Balance Sheet (US$m) | | | | | |
|---|---|---|---|---|---|
| Cash | 11.8 | 22.0 | 11.6 | 7.0 | 12.0 |
| Receivables | - | 0.1 | 0.5 | 1.7 | 3.4 |
| Short term investments | 0.3 | 0.3 | 0.3 | 0.3 | 0.4 |
| Other current assets | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| Property, Plant and Equipment | 0.3 | 0.4 | 0.5 | 0.6 | 0.7 |
| Intangible assets | 0.1 | 0.1 | 0.1 | 0.1 | 0.1 |
| **Total assets** | 12.6 | 23.0 | 13.1 | 9.8 | 16.7 |
| Trade payables /accruals | 1.0 | 1.0 | 1.1 | 2.2 | 4.5 |
| Other liabilities | - | - | - | - | - |
| Debt - interest bearing debt | - | - | - | - | - |
| **Total Liabilities** | 1.0 | 1.0 | 1.1 | 2.2 | 4.5 |
| **Net Assets** | 11.6 | 22.0 | 12.0 | 7.6 | 12.1 |
| Share capital | 64.8 | 85.8 | 85.8 | 85.8 | 85.8 |
| Retained earnings | (53.2) | (63.8) | (73.8) | (78.2) | (73.7) |
| Reserves | - | - | - | - | - |
| **Shareholders Equity** | 11.6 | 22.0 | 12.0 | 7.6 | 12.1 |

| Valuation Ratios (US$m) | FY15 | FY16e | FY17e | FY18e | FY19e |
|---|---|---|---|---|---|
| Reported EPS (cps) | -8.3 | -4.9 | -3.9 | -1.7 | 1.8 |
| Normalised EPS (cps) | -8.3 | -4.9 | -3.9 | -1.7 | 1.8 |
| EPS growth (%) | 19% | -42% | -20% | -55% | na |
| **PE(x)** | **-5.3** | **-9.1** | **-11.4** | **-25.2** | **24.7** |
| **EV/EBITDA (x)** | -7.3 | -8.1 | -8.6 | -18.3 | 21.4 |
| **EV/EBIT (x)** | -7.3 | -8.1 | -8.6 | -17.9 | 21.9 |
| | | | | | |
| NTA (cps) | 7.4 | 8.5 | 4.6 | 2.9 | 4.7 |
| P/NTA (x) | 5.9 | 5.2 | 9.5 | 15.2 | 9.4 |
| Book Value (cps) | 7.5 | 8.6 | 4.7 | 2.9 | 4.7 |
| Price/Book (x) | 5.9 | 5.1 | 9.4 | 15.0 | 9.3 |
| | | | | | |
| DPS (cps) | - | - | - | - | - |
| Payout ratio % | 0% | 0% | 0% | 0% | 0% |
| Dividend Yield % | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| Franking % | 170% | 0% | 0% | 0% | 0% |
| FCF yield % | -17% | -9% | -9% | -4% | 4% |
| | | | | | |
| 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 | 1H16 | 2H16e |
|---|---|---|
| Unit sales | 590 | 1,071 |
| Revenues | 0.2 | 0.4 |
| EBIT | -6.1 | -5.0 |
| NPAT | -6.1 | -4.5 |

SOURCE: BELL POTTER SECURITIES ESTIMATES

**Recommendation structure**

**Buy:** Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

**Hold:** Expect total return between -5% and 15% on a 12 month view

**Sell:** Expect <-5% total return on a 12 month view

*Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.*

*Such investments may carry an exceptionally high level of capital risk and volatility of returns.*

## Research Team

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