

O/W: Halting the metastatic issue cascade

We maintain our OVERWEIGHT rating on Oncosil Medical with a revised 12-month PT of \$0.17 per share. Oncosil's new leadership was tasked with much in its first eight months: a) fix the product's marketing label in Europe; b) redesign the reimbursement strategy to suit; c) finalise a Humanitarian Device Exemption application in the USA; and finally, d) agree on a pivotal trial design to support a US FDA approval. In retrospect, slippage was inevitable. Recent Board instability is ill timed and disconnects the OSL share price from fundamentals ahead of hard-won inflection points. Our FY21 review of operations confirms progress on all aspects described above. Access to development capital remains the key risk to the value of this promising clinical asset being realised for shareholders.

Key points

Evidence development in Europe. Oncosil has good plans to broaden its European label to better suit the chemotherapeutic standard of care in that region (FOLFIRINOX preferred to gemcitabine). KOL input seems to be pushing trial design towards: a) objective definitions for 'unresectable' pancreatic cancer; b) better standardisation of the chemotherapy active comparator; and c) a greater emphasis on 'quality of life', palliative endpoints including pain and tolerability. There is limited information available but we assess this may be achieved with a small randomised controlled trial (n <50) conducted in 10-15 European centres. The outcomes we've described would be useful additions to the CE Mark marketing label. Separately, the re-opening of activity in European hospitals has allowed reimbursement progress in several countries, targeting commercial sales from mid-2022.

HDE catalyst to support R&D investments. We view the potential 2022 humanitarian (HDE) approval in US for bile duct cancer favourably. This potential early marketing clearance holds more immediate commercial potential than Europe because it offers straightforward US reimbursement access, a lower evidence hurdle to revenue generation and the prospect of investigator-led, off-label experimentation with OncoSil™.

Valuation. Our \$0.17 per share valuation is based on a real-options DCF methodology that incorporates four critical regulatory steps for OncoSil™ commercialisation: a) HDE approval; b) IDE approval; c) PMA approval and d) market access including reimbursement. Our current unrisks valuation of OncoSil Medical is \$0.52 per share. The 34% price target reduction stems from revisions to our equity capital issuance assumptions. Oncosil closed FY21 with \$12M cash which is adequate to deliver a humanitarian approval (HDE) although the timing of that catalyst will likely slip into 1Q22, in our view.

Risks and catalysts

Risks: a) regulatory delays; b) lower than expected sales; c) access to development capital; d) reimbursement challenges; e) Board. **Catalysts:** a) first commercial sales; b) HDE regulatory progress; c) pivotal clinical trial progress; d) positive clinical performance.

| Earnings forecasts | | | | | |
|----------------------|-------|-------|-------|--------|-------|
| Year-end June (AUD) | FY20A | FY21A | FY22F | FY23F | FY24F |
| NPAT rep (\$m) | -4.3 | -10.3 | -3.9 | -11.4 | -12.1 |
| NPAT norm (\$m) | -4.3 | -10.4 | -3.9 | -11.4 | -12.1 |
| Consensus NPAT (\$m) | | | -10.3 | -12.3 | -7.1 |
| EPS norm (cps) | -0.6 | -1.3 | -0.4 | -1.1 | -1.1 |
| EPS growth (%) | 51.4 | -96.5 | 70.2 | -181.9 | 1.3 |
| P/E norm (x) | -7.9 | -4.0 | -13.4 | -4.8 | -4.8 |
| EV/EBITDA (x) | -6.6 | -2.8 | -6.8 | -2.4 | -2.3 |
| FCF yield (%) | -11.0 | -21.8 | -11.7 | -23.7 | -30.8 |
| DPS (cps) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Dividend yield (%) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Franking (%) | 0 | 0 | 0 | 0 | 0 |

Source: Company data, Wilsons estimates, Refinitiv

Wilsons Equity Research

Analyst(s) who own shares in the Company: n/a

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| Recommendation | OVERWEIGHT |
|--|---------------|
| 12-mth target price (AUD) | \$0.17 |
| Share price @ 18-Aug-21 (AUD) | \$0.05 |
| Forecast 12-mth capital return | 224.4% |
| Forecast 12-mth dividend yield | 0.0% |
| 12-mth total shareholder return | 224.4% |
| Market cap | \$41m |
| Enterprise value | \$29m |
| Shares on issue | 797m |
| Sold short | |
| ASX 300 weight | n/a |
| Median turnover/day | \$0.1m |

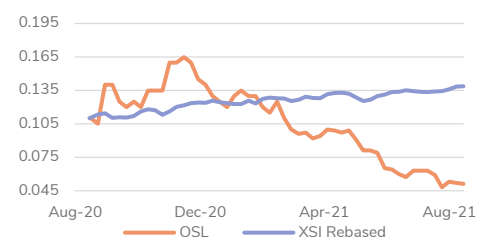
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12-mth price performance (\$)

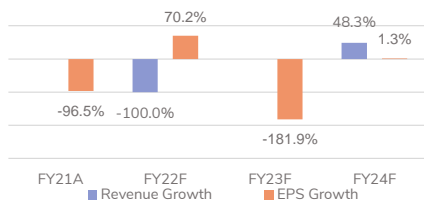


| | 1-mth | 6-mth | 12-mth |
|----------------|-------|-------|--------|
| Abs return (%) | -16.4 | -53.6 | -53.6 |
| Rel return (%) | -21.1 | -62.9 | -79.7 |

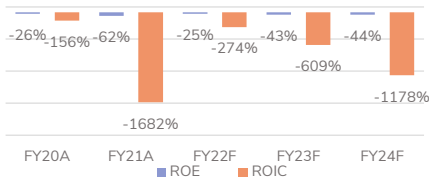
Key changes

| | | 22-Apr | After | Var % |
|--------------|-------|--------|-------|--------|
| NPAT: | FY22F | -11.6 | -3.9 | N/A |
| norm | FY23F | -12.1 | -11.4 | N/A |
| (\$m) | FY24F | | -12.1 | |
| EPS: | FY22F | -1.3 | -0.4 | N/A |
| norm | FY23F | -1.4 | -1.1 | N/A |
| (cps) | FY24F | | -1.1 | |
| DPS: | FY22F | 0.0 | 0.0 | 0.0% |
| (cps) | FY23F | 0.0 | 0.0 | 0.0% |
| | FY24F | | 0.0 | |
| Pricetarget: | | 0.25 | 0.17 | -33.8% |
| Rating: | | O/W | O/W | |

Growth rates



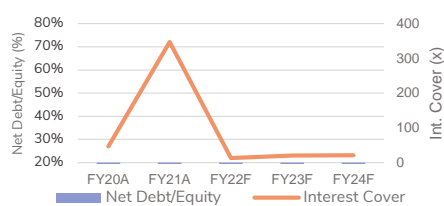
Returns



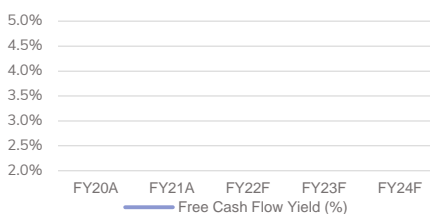
Margin trends



Solvency



Free cash flow yield



Interims (\$m)

| | 1H21A | 2H21A | 1H22E | 2H22E |
|-------------------|-------------|-------------|------------|-------------|
| Sales revenue | 0.1 | 0.1 | 0.0 | 0.0 |
| EBITDA | -4.6 | -5.7 | -0.2 | -4.1 |
| EBIT | -4.7 | -5.8 | -0.2 | -4.1 |
| Net profit | -4.7 | -5.7 | 0.0 | -3.9 |
| Norm EPS | -0.6 | -0.7 | 0.0 | -0.3 |
| EBIT/sales (%) | -5,058.7 | - | - | - |
| Dividend (c) | 0.0 | 0.0 | 0.0 | 0.0 |
| Franking (%) | 0.0 | 0.0 | 0.0 | 0.0 |
| Payout ratio (%) | 0.0 | 0.0 | 0.0 | 0.0 |
| Adj payout (%) | 0.0 | 0.0 | 0.0 | 0.0 |

Key assumptions

| | FY17A | FY18A | FY19A | FY20A | FY21A | FY22F | FY23F | FY24F |
|-----------------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|
| Revenue Growth (%) | | | | | | -100.0 | | 48.3 |
| EBIT Growth (%) | 46.9 | 20.0 | 1.0 | -50.3 | 140.2 | -59.4 | 181.0 | 5.9 |
| NPAT Growth (%) | 47.1 | 21.7 | 0.3 | -50.3 | 144.8 | -62.5 | 190.0 | 6.2 |
| EPS Growth (%) | 32.8 | 12.3 | -11.6 | -51.4 | 96.5 | -70.2 | 181.9 | -1.3 |
| Tax Rate (%) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| ROA (%) | -52.3 | -54.8 | -55.6 | -24.4 | -54.8 | -24.9 | -44.4 | -45.4 |
| ROE (%) | -56.3 | -60.4 | -59.4 | -26.2 | -62.1 | -25.0 | -42.9 | -44.2 |

Financial ratios

| | FY17A | FY18A | FY19A | FY20A | FY21A | FY22F | FY23F | FY24F |
|--------------------|-------|-------|-------|-------|-------|-------|-------|-------|
| PE (x) | -3.8 | -3.4 | -3.8 | -7.9 | -4.0 | -13.4 | -4.8 | -4.8 |
| EV/EBITDA (x) | -4.0 | -3.3 | -3.3 | -6.6 | -2.8 | -6.8 | -2.4 | -2.3 |
| Dividend yield (%) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| FCF yield (%) | -15.2 | -20.7 | -18.5 | -11.0 | -21.8 | -11.7 | -23.7 | -30.8 |
| Payout ratio (%) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Adj payout (%) | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |

Profit and loss (\$m)

| | FY17A | FY18A | FY19A | FY20A | FY21A | FY22F | FY23F | FY24F |
|-----------------------------------|-------------|-------------|-------------|-------------|--------------|-------------|--------------|--------------|
| Sales revenue | 0.0 | 0.0 | 0.0 | 0.0 | 0.2 | 0.0 | 0.7 | 1.1 |
| EBITDA | -7.2 | -8.6 | -8.8 | -4.3 | -10.3 | -4.2 | -11.9 | -12.6 |
| Depn & amort | 0.0 | 0.0 | 0.0 | 0.0 | 0.2 | 0.0 | 0.0 | 0.0 |
| EBIT | -7.2 | -8.7 | -8.8 | -4.4 | -10.5 | -4.3 | -11.9 | -12.7 |
| Net interest expense | -0.2 | -0.1 | -0.2 | -0.1 | 0.0 | -0.3 | -0.6 | -0.6 |
| Tax | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Minorities/pref divs | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Equity accounted NPAT | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Net profit (pre-sig items) | -7.0 | -8.5 | -8.6 | -4.3 | -10.4 | -3.9 | -11.4 | -12.1 |
| Abns/exts/signif | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Reported net profit | -7.0 | -8.5 | -8.6 | -4.3 | -10.3 | -3.9 | -11.4 | -12.1 |

Cash flow (\$m)

| | FY17A | FY18A | FY19A | FY20A | FY21A | FY22F | FY23F | FY24F |
|--------------------------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|--------------|
| EBITDA | -7.2 | -8.6 | -8.8 | -4.3 | -10.3 | -4.2 | -11.9 | -12.6 |
| Interest & tax | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | -0.3 | -0.6 | -0.6 |
| Working cap/other | 1.1 | 0.2 | 1.2 | -0.1 | 1.5 | 0.0 | 3.1 | 0.9 |
| Operating cash flow | -6.1 | -8.4 | -7.5 | -4.5 | -8.8 | -4.6 | -9.4 | -12.3 |
| Maintenance capex | -0.1 | 0.0 | 0.0 | 0.0 | -0.1 | -0.2 | -0.2 | -0.2 |
| Free cash flow | -6.2 | -8.4 | -7.5 | -4.5 | -8.9 | -4.8 | -9.6 | -12.5 |
| Dividends paid | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Growth capex | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Invest/disposals | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Oth investing/finance flows | 3.4 | -1.1 | 0.0 | -1.3 | 0.0 | 0.0 | 0.0 | 0.0 |
| Cash flow pre-financing | -2.7 | -9.5 | -7.5 | -5.8 | -8.9 | -4.8 | -9.6 | -12.5 |
| Funded by equity | 1.0 | 16.7 | 0.0 | 19.1 | 0.3 | 10.0 | 25.0 | 0.0 |
| Funded by debt | 0.0 | 0.0 | 0.1 | 0.0 | -0.1 | 0.0 | 0.0 | 0.0 |
| Funded by cash | 1.8 | -7.2 | 7.5 | -13.3 | 8.8 | -5.2 | -15.4 | 12.5 |

Balance sheet summary (\$m)

| | FY17A | FY18A | FY19A | FY20A | FY21A | FY22F | FY23F | FY24F |
|-----------------------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|
| Cash | 8.0 | 15.2 | 7.7 | 21.0 | 12.2 | 17.4 | 32.8 | 20.2 |
| Current receivables | 3.5 | 4.5 | 3.8 | 2.8 | 1.2 | 2.0 | 0.2 | 0.7 |
| Current inventories | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Net PPE | 0.1 | 0.1 | 0.1 | 0.1 | 0.5 | 0.5 | 0.7 | 0.8 |
| Intangibles/capitalised | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| Total assets | 11.8 | 19.9 | 11.7 | 24.1 | 14.2 | 20.0 | 33.8 | 22.0 |
| Current payables | 1.5 | 1.6 | 0.8 | 1.8 | 1.7 | 0.0 | 0.1 | 0.3 |
| Total debt | 0.0 | 0.0 | 0.0 | 0.0 | 0.5 | 0.0 | 0.0 | 0.0 |
| Total liabilities | 1.7 | 1.7 | 1.0 | 2.2 | 2.5 | 0.4 | 0.4 | 0.7 |
| Shareholder equity | 10.1 | 18.2 | 10.7 | 21.9 | 11.7 | 19.6 | 33.3 | 21.2 |
| Total funds employed | 10.1 | 18.2 | 10.7 | 21.9 | 12.2 | 19.6 | 33.3 | 21.2 |



Oncosil Medical (OSL)

Business description

Oncosil Medical Limited (OSL) is developing a novel form of brachytherapy for the treatment of pancreatic and liver cancers. OncoSil™ provides a means of irradiating tumours from the inside, using microparticles impregnated with the radioactive isotope Phosphorus-32. OncoSil™ has been granted a CE Mark for the device with first commercial sales being made in FY21. The device is the subject of a large pivotal clinical trial yet to commence (expected 2022) for US and further EU market entry. We estimate a US\$350m sales opportunity in the major pancreatic cancer markets.

Investment thesis

We maintain our OVERWEIGHT rating on Oncosil Medical with a revised 12-month PT of \$0.17 per share. Oncosil's new leadership is tasked with much in its first eight months: a) fix the product's marketing label in Europe; b) redesign the reimbursement strategy to suit; c) finalise a Humanitarian Device Exemption application in USA; and finally, d) agree a pivotal trial design to support a US FDA approval. In retrospect, slippage was inevitable. Recent Board instability is ill timed and disconnects the OSL share price from fundamentals ahead of hard-won inflection points. Our FY21 review of operations confirms progress on all aspects described above. Access to development capital remains the key risk to the value of this promising clinical asset being realised for shareholders.

Revenue drivers

- Clinical trial success and regulatory approvals to market their products
- Pricing and reimbursement decisions
- Market penetration (new clinical centres/hospitals, physician acceptance)
- New markets (geographical, clinical indications)

Margin drivers

- Gross margins sustainable at 80% or better
- Although SG&A structure is yet to evolve, long-term rates of ~40-50% achievable (Wilson's estimates)
- Reimbursement outcomes (pricing).

Key issues/catalysts

- European marketing and first revenues from private payers
- Pivotal trial initiation, execution, results and FDA approvals
- EU reimbursement coding (e.g. NICE)

Risk to view

- The technology is currently only supported by low level evidence from a handful of small Phase I/II clinical trials or single-arm studies.
- Outlook depends on higher level clinical evidence flowing from well-designed clinical trials which they are now undertaking.
- Product safety.
- Competitive risks in a busy oncology technology market.
- Complexity of clinician adoption given collaborative approach required.

Balance sheet

- As at end FY21 Oncosil had ~\$12M in cash and no debt.

Board

- Dr Chris Roberts (Chairman)
- Nigel Lange (Managing Director)
- Dr Roger Aston (Non-Executive Director)
- Dr Martin Cross (Non-Executive Director)
- Michael Bassett (Non-Executive Director)
- Otto Buttula (Non-Executive Director)

Management

- Nigel Lange (CEO)
- Karl Pechmann (CFO)
- Dr Ralph Peters (Chief Medical Officer, CMO)
- David Turner (Head of Medical Affairs)
- David James (Global Head of Manufacturing and Operations)
- Henk Tissing (Director of Global Clinical Affairs)
- Michael Warrener (Director of Sales and Marketing)
- Nicole Wilson (VP Regulatory Affairs and Quality)
- Charles Rowland (President – US Operations)
- Olaf Michaelsen (Director of Access Reimbursement, Economics, Assessment)

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Definitions at wilsonsadvisory.com.au/disclosures.

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