Date
30 January 2020

Theme
Company Update

Company
Oncosil Medical (OSL)

WILSONS

OVERWEIGHT: Upgrade anticipating European approval

We move further OVERWEIGHT Oncosil anticipating imminent European approval for OncoSil™. The company continued to work with regulators over the break to finalise its post-approval plans. If successful, the product will become commercially available in Europe for the treatment of pancreatic cancer. Separately, Oncosil's pursuit of a humanitarian approval in the USA remains on track as another source of potential income this year. These unexpected but welcome reversals of fortune mean that Oncosil's valuation is reconnecting with fundamentals. Our new price target is $0.30 per share (+62%). Catalysts over the next 3-4 years could support valuation gains up to $1.20 per share (un-risked asset value, fully diluted basis).

Key points

European approval imminent. We have moved further OVERWEIGHT OSL because the clinical trial data supporting their OncoSil™ product has continued to improve in terms of patient survival. Changes to the European medical device approval process has been a systemic challenge for all developers over the last 12 months. We understand that Oncosil's journey has reached 'post-approval' matters so we are confident of an approval this half. In the meantime, the welcome longevity of pancreatic cancer patients treated in the company's PanCO trial has been driving further improvements in the study's clinical and statistical performance. These encouraging results should help drive initial demand for the product, once the formal marketing approvals are granted.

USA regulatory outlook. In the USA, an early path to market has opened. Bile duct cancers are both rarer and often carry a poorer prognosis than pancreatic cancers. OncoSil™'s humanitarian potential is worth exploring in this setting. Contemporary brachytherapy company BTG plc made a US$90m business from a humanitarian approval for their *TheraSpheres* device in similar circumstances. If successful, Oncosil could access US sales from 2H 2020. Oncosil must still pursue its formal program of 'pivotal' clinical trials in USA but this opportunistic new business could prove helpful in terms of project financing, product awareness and establishing US pricing for OncoSil™.

Valuation upgrade. We have increased the probability of European approval to 90% (compared with 60% prior to receipt of a positive CE Mark Status Report). That change drives a 62% increase in price target to $0.30/share. Further catalysts over the next 12 months (humanitarian approval, FDA clearance for US clinical trial) may support price targets up to $0.40/share. Catalysts over the next 3-4 years (pivotal clinical trial success, US marketing approval) could move valuation closer to 'un-risked' basis of $1.20/share.

Risks and catalysts described on p.5 of this report

Recommendation	**OVERWEIGHT**
12-mth target price (AUD)	**$0.30**
Share price @ 29-Jan-20 (AUD)	$0.17
Forecast 12-mth capital return	76.5%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	**76.5%**
Market cap	$107m
Enterprise value	$82m
Shares on issue	631m
Sold short	
ASX 300 weight	n/a
Median turnover/day	$0.1m

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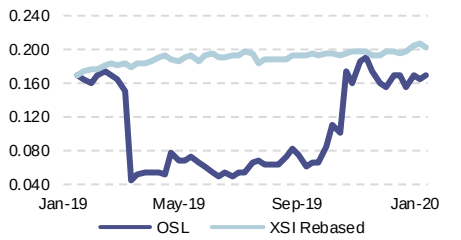
FUNDAMENTAL INSIGHTS

12-mth price performance ($)



	1-mth	6-mth	12-mth
Abs return (%)	0.0	161.5	0.0
Rel return (%)	-1.8	159.3	-19.3

Earnings forecasts

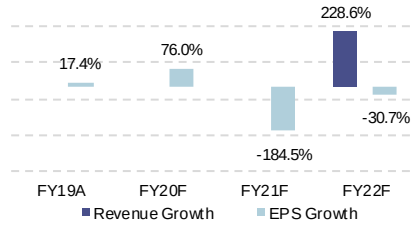
Year-end June (AUD)	FY18A	FY19A	FY20F	FY21F	FY22F
NPAT rep ($m)	-8.5	-8.6	-2.7	-8.1	-10.6
NPAT norm ($m)	-8.5	-8.6	-2.7	-8.1	-10.6
Consensus NPAT ($m)			-8.1	-13.7	-17.2
EPS norm (cps)	-1.6	-1.4	-0.3	-0.9	-1.2
EPS growth (%)	-11.5	17.4	76.0	-184.5	-30.7
P/E norm (x)	-10.3	-12.5	-52.1	-18.3	-14.0
EV/EBITDA (x)	-9.5	-9.4	-29.6	-9.6	-7.4
FCF yield (%)	-7.8	-7.0	-2.6	-8.5	-9.9
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, S&P Capital IQ

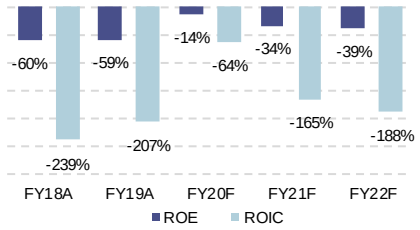
Key changes

		01-Nov	After	Var %
NPAT:	**FY20F**	-2.8	-2.7	N/A
norm	**FY21F**	-8.8	-8.1	N/A
($m)	**FY22F**	-12.1	-10.6	N/A
EPS:	**FY20F**	-0.3	-0.3	N/A
norm	**FY21F**	-1.0	-0.9	N/A
(cps)	**FY22F**	-1.4	-1.2	N/A
DPS:	**FY20F**	0.0	0.0	0.0%
(cps)	**FY21F**	0.0	0.0	0.0%
	FY22F	0.0	0.0	0.0%
Price target:		0.19	0.30	61.9%
Rating:		**O/W**	**O/W**	

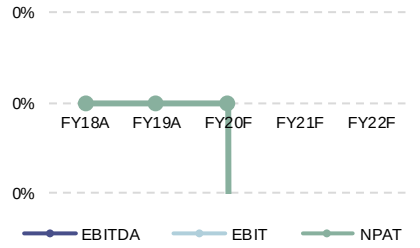
Growth rates



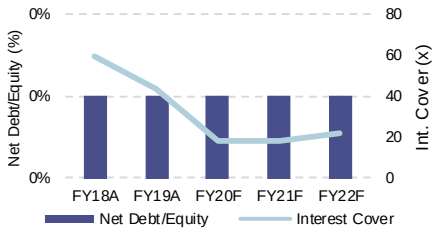
Returns



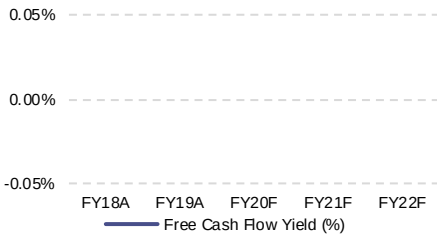
Margin trends



Solvency



Free cash flow yield



Interims ($m)

	1H19A	2H19A	1H20E	2H20E
Sales revenue	0.0	0.0	0.0	0.0
EBITDA	-5.2	-3.5	-0.3	-2.5
EBIT	-5.3	-3.5	-0.3	-2.5
Net profit	**-5.1**	**-3.4**	**-0.2**	**-2.5**
Norm EPS	**-0.8**	**-0.5**	**0.0**	**-0.3**
EBIT/sales (%)				
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

	FY15A	FY16A	FY17A	FY18A	FY19A	FY20F	FY21F	FY22F
Revenue Growth (%)								228.6
EBIT Growth (%)	-35.9	62.5	46.9	20.0	1.0	-68.0	205.5	29.5
NPAT Growth (%)	-31.7	65.6	47.1	21.7	0.3	-69.1	205.8	30.7
EPS Growth (%)	**-40.4**	**38.7**	**31.4**	**11.5**	**-17.4**	**-76.0**	**184.5**	**30.7**
EBIT / Sales (%)							-1,225.5	-483.0
Tax Rate (%)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ROA (%)	**-30.8**	**-42.3**	**-52.3**	**-54.8**	**-55.6**	**-14.0**	**-35.2**	**-40.2**
ROE (%)	**-30.1**	**-43.8**	**-56.3**	**-60.4**	**-59.4**	**-13.7**	**-33.8**	**-39.1**

Financial ratios

	FY15A	FY16A	FY17A	FY18A	FY19A	FY20F	FY21F	FY22F
PE (x)	-21.0	-15.1	-11.5	-10.3	-12.5	-52.1	-18.3	-14.0
EV/EBITDA (x)	-27.2	-16.8	-11.4	-9.5	-9.4	-29.6	-9.6	-7.4
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FCF yield (%)	-0.2	-4.3	-5.7	-7.8	-7.0	-2.6	-8.5	-9.9
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)

	FY15A	FY16A	FY17A	FY18A	FY19A	FY20F	FY21F	FY22F
Sales revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.7	2.3
EBITDA	-3.0	-4.9	-7.2	-8.6	-8.8	-2.8	-8.6	-11.1
Depn & amort	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EBIT	**-3.0**	**-4.9**	**-7.2**	**-8.7**	**-8.8**	**-2.8**	**-8.6**	**-11.1**
Net interest expense	-0.2	-0.2	-0.2	-0.1	-0.2	-0.2	-0.5	-0.5
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)	**-2.9**	**-4.8**	**-7.0**	**-8.5**	**-8.6**	**-2.7**	**-8.1**	**-10.6**
Abns/exts/signif	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Reported net profit	**-2.9**	**-4.8**	**-7.0**	**-8.5**	**-8.6**	**-2.7**	**-8.1**	**-10.6**

Cash flow ($m)

	FY15A	FY16A	FY17A	FY18A	FY19A	FY20F	FY21F	FY22F
EBITDA	-3.0	-4.9	-7.2	-8.6	-8.8	-2.8	-8.6	-11.1
Interest & tax	2.8	0.0	0.0	0.0	0.0	-0.2	-0.5	-0.5
Working cap/other	0.1	0.3	1.1	0.2	1.2	0.3	0.2	1.2
Operating cash flow	**-0.2**	**-4.6**	**-6.1**	**-8.4**	**-7.5**	**-2.6**	**-8.9**	**-10.4**
Maintenance capex	0.0	-0.1	-0.1	0.0	0.0	-0.2	-0.2	-0.2
Free cash flow	**-0.2**	**-4.6**	**-6.2**	**-8.4**	**-7.5**	**-2.8**	**-9.1**	**-10.6**
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	0.0	-0.5	3.4	-1.1	0.0	0.0	0.0	0.0
Cash flow pre-financing	**-0.2**	**-5.1**	**-2.7**	**-9.5**	**-7.5**	**-2.8**	**-9.1**	**-10.6**
Funded by equity	0.0	12.4	1.0	16.7	0.0	20.0	0.0	25.0
Funded by debt	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0
Funded by cash	0.2	-7.3	1.8	-7.2	7.5	-17.2	9.1	-14.4

Balance sheet summary ($m)

	FY15A	FY16A	FY17A	FY18A	FY19A	FY20F	FY21F	FY22F
Cash	2.5	9.8	8.0	15.2	7.7	24.9	15.8	30.2
Current receivables	0.1	2.6	3.5	4.5	3.8	3.2	4.0	4.0
Current inventories	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1
Net PPE	0.1	0.1	0.1	0.1	0.1	0.2	0.4	0.6
Intangibles/capitalised	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total assets	**7.4**	**15.9**	**11.8**	**19.9**	**11.7**	**28.4**	**20.3**	**34.9**
Current payables	0.2	1.0	1.5	1.6	0.8	0.2	0.2	0.4
Total debt	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total liabilities	**0.4**	**1.1**	**1.7**	**1.7**	**1.0**	**0.4**	**0.4**	**0.6**
Shareholder equity	**7.0**	**14.8**	**10.1**	**18.2**	**10.7**	**28.0**	**19.9**	**34.3**
Total funds employed	**7.0**	**14.8**	**10.1**	**18.2**	**10.7**	**28.0**	**19.9**	**34.3**

Oncosil Medical – Upgrading anticipating EU approval

Investment Thesis

European regulatory process nearing positive conclusion. Oncosil continues to work with regulatory authorities to make OncoSil™ commercially available for patients in Europe this year. We understand that the company's submissions in relation to post-approval commitments are now in the final stages of review. They follow the positive CE Mark Status Report announced in November. Our forecasts and valuation are predicated on European approvals in the current quarter and European launches in FY21. Note that a CE Mark may open up subsequent approvals in other jurisdictions including Australia, New Zealand, Singapore, Malaysia and Hong Kong.

Trial data to support initial clinical adoption and sales. The time delay in approval has allowed some aspects of the company's PanCo clinical trial to mature. A number of successfully treated patients remain alive and their longevity thus extends the 'median overall survival' associated with treatment. Recall that 10 of 42 patients responded well enough to undergo surgical removal of their primary tumour, having previously been classified as 'unresectable'. As at the company's AGM update, median overall survival was 15.5 months and improving. PanCO results suggested that the combination of OncoSil™ and chemotherapy may be superior to chemotherapy alone across the range of primary and secondary clinical measures investigated. The safety and reproducibility of OncoSil™ appears to be very good. We believe the product will find initial demand this year, assuming the CE Mark process ends successfully.

Pivotal trial plans emerging in USA. The path to market in USA will entail a larger scale, adequately controlled clinical trial. Oncosil's dialogue with FDA will soon return to this study, aiming to agree on its design features (number of patients, clinical objectives). Investors should welcome this clarity in terms of understanding the capital commitments, timing and potential pay-offs from US market entry.

Early US market entry via humanitarian route. In October 2019, the US FDA granted OncoSil™ a Humanitarian Use Designation (HUD) for the treatment of both intrahepatic and distal cholangiocarcinoma. The company is now in a position to file for Humanitarian Device Exemptions (HDEs) which confer restricted marketing rights. We estimate ~5,500 new cases of cholangiocarcinoma are diagnosed in the USA, annually. Most patients die within 12 months because these primary tumours are often diagnosed late and are lethal. US law exempts HDE devices from demonstrating a reasonable assurance of effectiveness and instead, requires demonstration of a probable benefit only.

FDA has already formed a positive view on OncoSil™ safety, as demonstrated by the PanCO trial. Oncosil will need to satisfy FDA that adequate post-treatment safety monitoring and follow-up will be put in place with appropriate resourcing and training. We are anticipating HDE filings late in the first half of 2020, setting up potential clearances in the last quarter, noting a 75-day review phase.

Valuation

Upgrading price target to $0.30/share. Commercialisation timelines have shifted on account of regulatory and project delays – but the underlying value in the OncoSil™ asset is unchanged. The magnitude and relevance of potential clinical benefit is perhaps stronger, following PanCO. The intellectual property rights underwriting asset value have also likely improved as the device's mechanism of action has become clearer.

Key valuation assumptions

- Total addressable market (TAM) in pancreatic cancer treatment approximately US$1.2B in annual product sales.
- Peak sales assumption of US$350m or ~29% of TAM, allowing for physician education, alternative treatments, gaps in reimbursement coverage and other market access factors.
- European launch in 2020 following CE Mark.
- USA launch in 2024 following FDA approval of a Pre-Marketing Authorisation application based on successful pivotal clinical trial.

Valuation methodology

- Formal earnings projections to 2035.
- Value of future, after tax cash flows as at 2024 launch is approximately A$865m.
- Target price hinges around four key events: a) CE Mark granting; b) FDA granting an Investigational Device Exemption allowing a pivotal clinical trial in USA; c) successful US pivotal trial results in late 2023; and d) FDA approval and market access from 2024.
- Shifting the near term CE Mark success probability from 60% (previously) to 90% gives a 29% lift in price target to $0.30/share.
- Further de-risking over the next 12 months support price targets up to $0.40/share – in line with our price target before the regulatory setbacks of 2019.
- Unrisked valuation (all probabilities set to 100%) is approximately $1.20/share on a fully diluted basis (3-4 year view).
- Valuation makes certain assumptions relating to equity funding for the project.

Table 1: Stagewise valuation profile for OncoSil™

OncoSil™				
Valuaton event	**CE Mark**	**FDA IDE**	**US Clinical Trial**	**Market Access**
Estimated probabilities (p)	90%	80%	60%	80%
Estimated timing	1H 2020	2H 2020	end-2023	2024
S+ (upside values, A$m)	227	293	681	865
Real option values (A$m)	**202**	**227**	**293**	**681**
Value per share (diluted, A$/share)	**0.30**			

Source: Wilsons

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™ is expected to be granted CE Mark in early 2020 and be the subject of a large clinical trial in the US commencing in 2020. We estimate a US$350m sales opportunity in the major pancreatic cancer markets.

Investment thesis

We move further OVERWEIGHT Oncosil anticipating imminent European approval for OncoSilTM. The company continued to work with regulators over the break to finalise its post-approval plans. If successful, the product will become commercially available in Europe for the treatment of pancreatic cancer. Separately, Oncosil's pursuit of a humanitarian approval in the USA remains on track as another source of potential income this year. These unexpected but welcome reversals of fortune mean that Oncosil's valuation is reconnecting with fundamentals. Our new price target is $0.30 per share (+62%). Catalysts over the next 3-4 months could support valuation gains up to $1.20 per share (un-risked asset value, fully diluted basis).

Revenue drivers

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

Balance sheet

- We estimate Oncosil will have cash and equivalents of ~$8m as at the end of FY20.

Margin drivers

- Gross margins sustainable at 80% or better
- Although SG&A structure is yet to evolve, long-term rates of ~40-60% achievable (Wilsons estimates)
- Reimbursement outcomes (pricing)

Board

- Dr Chris Roberts (Chairman)
- Daniel Kenny (Managing Director)
- Dr Roger Aston (Non-Executive Director)
- Martin Cross (Non-Executive Director)
- Michael Basset (Non-Executive Director)

Key issues/catalysts

- CE Marking and European marketing
- Clinical trial execution, results and FDA approvals
- Potential for commercial partnering interest over the next few years as OncoPac-1 trial gains momentum

Management

- Daniel Kenny (CEO)

Risk to view

- The technology is currently only supported by low level evidence from a handful of small Phase I/II clinical trials
- Outlook depends on higher level clinical evidence flowing from well-designed clinical trials
- Regulatory risks including manufacturing and quality issues
- Product safety
- Competitive risks in a busy oncology technology market

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Disclaimers and disclosures

Recommendation structure and other definitions

Definitions at wilsonsadvisory.com.au/Disclosures.

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