Date
01 April 2020

Theme
Company Update

Company
Oncosil Medical (OSL)

WILSONS

OVERWEIGHT: CE Mark for OncoSil

We move further OVERWEIGHT following the grant of CE Mark for OncoSil™. Our new price target is $0.43 per share. Later this year, OncoSil™ will become commercially available in Europe for the treatment of locally advanced pancreatic cancer. Approval options may also be exercised in other parts of the world under mutual recognition agreements. Separately, Oncosil's pursuit of a humanitarian approval in the USA remains on track as another source of potential income starting in 2020. The next major clinical catalyst is the finalisation of pivotal trial plans with FDA and the start of the formal US approval campaign.

Key points

CE Mark granted. Oncosil has announced the European CE Mark approval for OncoSil™. The company is planning commercial launches in Europe and other jurisdictions late this calendar year. The approved indication is for the treatment of locally advanced pancreatic cancer in combination with chemotherapy. OncoSil™ has been granted a breakthrough designation.

COVID-19 granting time to develop multijurisdictional sales and logistics. Oncosil had planned to launch from July but the pandemics impact on hospitals may see that deferred to the last quarter of 2020. In the meantime CE Mark allows parallel marketing applications in other jurisdictions which have mutual recognition with Europe including ASEAN and APAC. We understand that 10 centres are already ready to accept product. The company is working on initiating a pipeline of other hospitals, preparing them for broader launch.

US humanitarian campaign stepping up. With this major regulatory milestone achieved, resource can now be applied to securing a Humanitarian Device Exemption (HDE) for the treatment of other rare biliary tumours. We expect submissions my mid-2020 and FDA clearance in 4Q2020.

US pivotal trial campaign supplemented by real world data in Europe. A full FDA clearance for pancreatic cancer treatment in USA requires a pivotal trial. Oncosil aims to complete discussions with FDA this year to define the clinical trial design and endpoints. Oncosil will conduct a post-marketing surveillance exercise as a condition of their European approval – a program that follows patients post treatment, documenting safety and efficacy in a 'real world' context. These data will be a valuable component of a Pre-market Authorisation (PMA) application for US marketing approval.

Valuation. We have moved our price target up by 43% to $0.43/share having 'de-risked' the grant of CE Mark in our valuation. Further upside is available this year as US market access under HDE and as the company's pivotal clinical trial plans are confirmed.

Recommendation	**OVERWEIGHT**
12-mth target price (AUD)	**$0.43**
Share price @ 01-Apr-20 (AUD)	$0.17
Forecast 12-mth capital return	152.6%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	**152.6%**
Market cap	$107m
Enterprise value	$86m
Shares on issue	631m
Sold short	
ASX 300 weight	n/a
Median turnover/day	$0.2m

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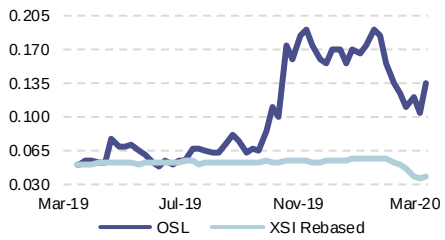
FUNDAMENTAL INSIGHTS

12-mth price performance ($)



	1-mth	6-mth	12-mth
Abs return (%)	8.0	107.7	170.0
Rel return (%)	31.8	136.0	192.3

Earnings forecasts

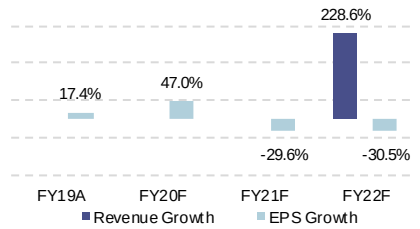
Year-end June (AUD)	FY18A	FY19A	FY20F	FY21F	FY22F
NPAT rep ($m)	-8.5	-8.6	-5.9	-8.2	-10.7
NPAT norm ($m)	-8.5	-8.6	-5.9	-8.2	-10.7
Consensus NPAT ($m)			-5.2	-12.3	-12.6
EPS norm (cps)	-1.6	-1.4	-0.7	-0.9	-1.2
EPS growth (%)	-11.5	17.4	47.0	-29.6	-30.5
P/E norm (x)	-10.3	-12.5	-23.6	-18.2	-13.9
EV/EBITDA (x)	-9.9	-9.8	-14.3	-10.0	-7.7
FCF yield (%)	-7.8	-7.0	-5.6	-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

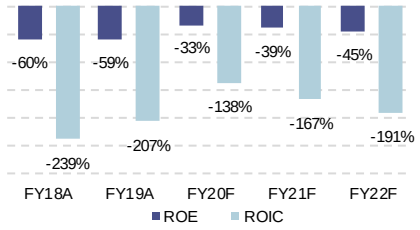
Key changes

		30-Jan	After	Var %
NPAT:	**FY20F**	-2.7	-5.9	>99%
norm	**FY21F**	-8.1	-8.2	N/A
($m)	**FY22F**	-10.6	-10.7	N/A
EPS:	**FY20F**	-0.3	-0.7	>99%
norm	**FY21F**	-0.9	-0.9	N/A
(cps)	**FY22F**	-1.2	-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:		0.30	0.43	43.2%
Rating:		**O/W**	**O/W**	

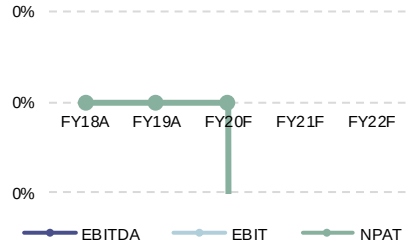
Growth rates



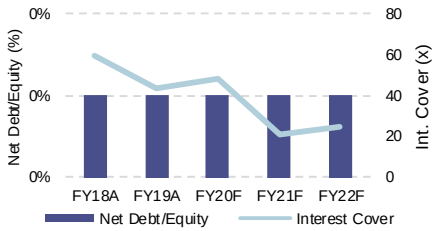
Returns



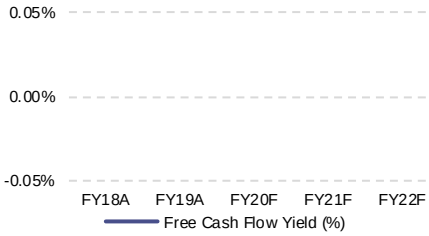
Margin trends



Solvency



Free cash flow yield



Interims ($m)

	1H19A	2H19A	1H20A	2H20E
Sales revenue	0.0	0.0	0.0	0.0
EBITDA	-5.2	-3.5	-3.4	-2.5
EBIT	-5.3	-3.5	-3.5	-2.5
Net profit	**-5.1**	**-3.4**	**-3.4**	**-2.5**
Norm EPS	**-0.8**	**-0.5**	**-0.5**	**-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	-31.7	43.2	29.5
NPAT Growth (%)	-31.7	65.6	47.1	21.7	0.3	-31.5	39.3	30.5
EPS Growth (%)	**-40.4**	**38.7**	**31.4**	**11.5**	**-17.4**	**-47.0**	**29.6**	**30.5**
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**	**-32.4**	**-40.4**	**-45.5**
ROE (%)	**-30.1**	**-43.8**	**-56.3**	**-60.4**	**-59.4**	**-33.0**	**-39.4**	**-44.8**

Financial ratios

	FY15A	FY16A	FY17A	FY18A	FY19A	FY20F	FY21F	FY22F
PE (x)	-16.7	-12.0	-9.1	-8.2	-9.9	-18.7	-14.4	-11.1
EV/EBITDA (x)	-28.3	-17.5	-11.9	-9.9	-9.8	-14.3	-10.0	-7.7
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	-5.6	-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	-6.0	-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**	**-6.0**	**-8.6**	**-11.1**
Net interest expense	-0.2	-0.2	-0.2	-0.1	-0.2	-0.1	-0.4	-0.4
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**	**-5.9**	**-8.2**	**-10.7**
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**	**-5.9**	**-8.2**	**-10.7**

Cash flow ($m)

	FY15A	FY16A	FY17A	FY18A	FY19A	FY20F	FY21F	FY22F
EBITDA	-3.0	-4.9	-7.2	-8.6	-8.8	-6.0	-8.6	-11.1
Interest & tax	2.8	0.0	0.0	0.0	0.0	-0.1	-0.4	-0.4
Working cap/other	0.1	0.3	1.1	0.2	1.2	0.2	0.0	1.1
Operating cash flow	**-0.2**	**-4.6**	**-6.1**	**-8.4**	**-7.5**	**-5.9**	**-8.9**	**-10.5**
Maintenance capex	0.0	-0.1	-0.1	0.0	0.0	-0.1	-0.2	-0.2
Free cash flow	**-0.2**	**-4.6**	**-6.2**	**-8.4**	**-7.5**	**-6.1**	**-9.1**	**-10.7**
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**	**-6.1**	**-9.1**	**-10.7**
Funded by equity	0.0	12.4	1.0	16.7	0.0	20.1	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	-14.0	9.1	-14.3

Balance sheet summary ($m)

	FY15A	FY16A	FY17A	FY18A	FY19A	FY20F	FY21F	FY22F
Cash	2.5	9.8	8.0	15.2	7.7	21.7	12.6	26.9
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	0.3	0.5
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**	**25.3**	**17.1**	**31.7**
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**	**24.8**	**16.7**	**31.0**
Total funds employed	**7.0**	**14.8**	**10.1**	**18.2**	**10.7**	**24.8**	**16.7**	**31.0**

Oncosil Medical (OSL) – CE Mark and commercialisation

We have consistently been confident in the likelihood of a European approval for OncoSil™. The clinical data that supports OncoSil™ has continued to improve in terms of patient survival, and changes to the European medical device approval process has been a systemic challenge for developers over the last 12-18 months. This is the product's first major market approval and serves as strong validation of the therapeutic concept.

Long term launch outlook maintained, in spite of near-term disruption from COVID19. The PanCo trial has driven improvements in the study's clinical and statistical performance. These encouraging results should help drive initial demand for the product, especially in a patient group with such limited treatment options. COVID19 will impact initial launch preparedness and delay the European launch, since OSL representatives will have limited hospital access to market the product to physicians, and provide training and equipment calibration. Already on-boarded sites may provide an incremental source of revenues in the near-term, with a full launch planned closer to October (delayed from the previously assessed July target). The company will continue to provide educational and digital marketing to European physicians to drive initial marketing and awareness efforts.

Anticipated international approvals provide additional growth opportunity. Management will commence registration filings in companies that recognize CE Mark certification to increase the number of jurisdictions where OncoSil™ will be commercially available including Australia, Singapore and Hong Kong.

USA regulatory outlook remains, trials will continue to progress. 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™.

Oncosil Medical (OSL)

Business description

Oncosil Medical Limited (OSL) is developing a novel form of brachytherapy for the treatment of pancreatic and liver cancers. OncoSilTM provides a means of irradiating tumours from the inside, using microparticles impregnated with the radioactive isotope Phosphorus-32. OncoSilTM 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 following the grant of CE Mark for OncoSil™. Our new price target is $0.43 per share. Later this year, OncoSil™ will become commercially available in Europe for the treatment of locally advanced pancreatic cancer. Approval options may also be exercised in other parts of the world under mutual recognition agreements. Separately, Oncosil's pursuit of a humanitarian approval in the USA remains on track as another source of potential income. The next major clinical catalyst is the finalisation of pivotal trial plans with FDA and the start of the formal US approval campaign).

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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Recommendation structure and other definitions

Definitions at wilsonsadvisory.com.au/Disclosures.

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