WILSONS
Equity Research

Date
03 September 2020

Theme
Company Update

Company
Oncosil Medical (OSL)

O/W: US HDE approval should re-rate stock

We maintain our OVERWEIGHT rating and $0.40 price target on Oncosil Medical. A US FDA humanitarian clearance later this year could re-rate the stock. HDE is a niche form of approval but it offers OncoSil™ a uniformity and immediacy in market access terms that will take years to develop in Europe/AsiaPac. It also offers investors ample precedent approvals to examine as predicates. The most relevant is Boston Scientific's TheraSphere business in liver cancer which has operated for over 20 years under a HDE. There is some residual uncertainty as to the scope of Oncosil's US pivotal trial campaign (in pancreatic cancer) but all the signals point to that study being smaller than originally envisaged.

Recommendation	**OVERWEIGHT**
12-mth target price (AUD)	**$0.40**
Share price @ 02-Sep-20 (AUD)	$0.12
Forecast 12-mth capital return	233.3%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	**233.3%**
Market cap	$99m
Enterprise value	$90m
Shares on issue	829m
Sold short	
ASX 300 weight	n/a
Median turnover/day	$0.2m

Key points

Balance sheet runway into FY21 sales debuts. Oncosil started FY21 with $21M cash, minimal R&D spend (for now) and marketing authorisations in the UK, EU, Singapore, Malaysia and NZ. Approvals are pending in Australia and Hong Kong. We understand that first commercial (paid) treatments could be scheduled as early as October, likely conducted at sites that have had scientific and clinical engagement since inception (London, Singapore). The manufacturing and supply infrastructure is ready to supply into those territories. Freight constraints into USA should resolve in time for launch in early 2021, assuming FDA grants approval under Humanitarian Device Exemption (HDE).

TheraSphere's HDE the predicate to think about. Boston Scientific's TheraSphere business (~US$85M annual net sales in 2018, previously owned by BTG plc and Nordion) has operated in the USA for more than 20 years under a HDE approval for liver cancer. Note that only ~50% of sales relate to the formal, HDE-approved indication. The balance reflects off-label use in metastatic colorectal cancer and neuroendocrine tumours. If successful with its HDE application, OncoSil™ use is most likely to occur within tertiary referral centres for hepatobiliary tumours. Off-label use in pancreatic cancer may develop in those settings as evidence develops. Oncosil's global OSPREY Registry is set to start in October. OSPREY will follow 500 patients for 7 years (with interim analysis).

US pivotal trial. As a reminder, overall survival in PanCO trial had reached 16 months as at May-19. That benefit continues to improve and subsequent updates are planned. A US pivotal trial is scheduled for 2021. Our assumption is ~180 patients randomised 1:1 to chemotherapy ± adjuvant OncoSil™. The pivotal trial may offer oncologists freedom in choosing which 'backbone' chemotherapy to combine with OncoSil™. The US marketing label may therefore be agnostic on chemo regimen.

Valuation. $0.40 price target based on DCF valuation of OncoSil™'s commercialisation for locally advanced pancreatic cancer in the major markets. The catalysts over the next 12 months include major market approvals and first sales validating clinical demand.

Risks and catalysts described on p.3 of this report

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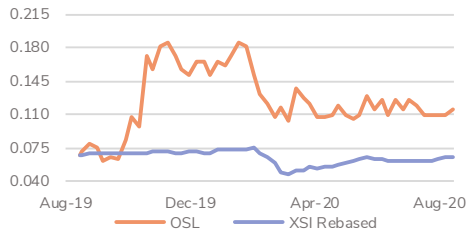
12-mth price performance ($)



	1-mth	6-mth	12-mth
Abs return (%)	4.5	-17.9	66.7
Rel return (%)	-3.0	-17.0	70.4

Earnings forecasts

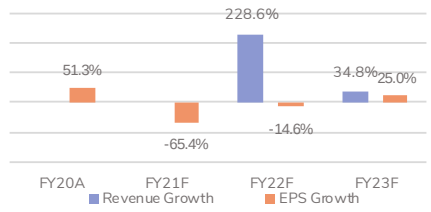
Year-end June (AUD)	FY19A	FY20A	FY21F	FY22F	FY23F
NPAT rep ($m)	-8.6	-4.3	-8.2	-10.7	-8.2
NPAT norm ($m)	-8.6	-4.3	-8.2	-10.7	-8.2
Consensus NPAT ($m)			-7.8	-11.2	
EPS norm (cps)	-1.4	-0.6	-1.1	-1.2	-0.9
EPS growth (%)	17.4	52.3	-65.4	-14.6	25.0
P/E norm (x)	-8.8	-18.5	-11.2	-9.8	-13.0
EV/EBITDA (x)	-10.2	-20.7	-10.5	-8.1	-10.4
FCF yield (%)	-7.6	-4.5	-11.3	-10.8	-5.5
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

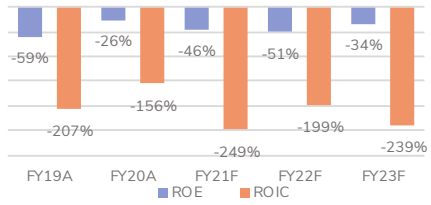
Key changes

		29-Jul	After	Var %
NPAT:	**FY21F**	-8.2	-8.2	N/A
norm	**FY22F**	-10.7	-10.7	N/A
($m)	**FY23F**		-8.2	
EPS:	**FY21F**	-1.0	-1.1	N/A
norm	**FY22F**	-1.2	-1.2	N/A
(cps)	**FY23F**		-0.9	
DPS:	**FY21F**	0.0	0.0	0.0%
(cps)	**FY22F**	0.0	0.0	0.0%
	FY23F		0.0	
Price target:		0.40	0.40	0.0%
Rating:		O/W	O/W	

Growth rates

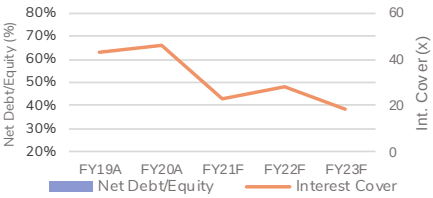


Returns

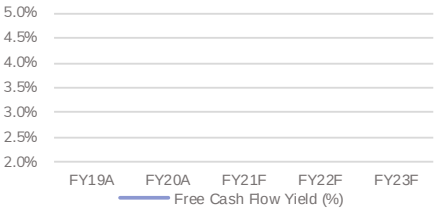


Margin trends

Solvency



Free cash flow yield



Interims ($m)

	1H20A	2H20A	1H21E	2H21E
Sales revenue	0.0	0.0	0.1	0.6
EBITDA	-3.4	-0.9	-2.8	-5.8
EBIT	-3.5	-0.9	-2.8	-5.8
Net profit	**-3.4**	**-0.9**	**-2.6**	**-5.6**
Norm EPS	**-0.5**	**-0.2**	**-0.4**	**-0.7**
EBIT/sales (%)			-	-966.5
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

	FY16A	FY17A	FY18A	FY19A	FY20A	FY21F	FY22F	FY23F
Revenue Growth (%)							228.6	34.8
EBIT Growth (%)	62.5	46.9	20.0	1.0	-50.3	96.9	29.5	-22.0
NPAT Growth (%)	65.6	47.1	21.7	0.3	-50.3	92.5	30.6	-23.6
EPS Growth (%)	**38.7**	**31.4**	**11.5**	**-17.4**	**-52.3**	**65.4**	**14.6**	**-25.0**
EBIT / Sales (%)						-1,225.5	-483.0	-279.4
Tax Rate (%)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ROA (%)	**-42.3**	**-52.3**	**-54.8**	**-55.6**	**-24.4**	**-44.8**	**-51.7**	**-35.0**
ROE (%)	**-43.8**	**-56.3**	**-60.4**	**-59.4**	**-26.2**	**-46.1**	**-51.4**	**-34.3**

Financial ratios

	FY16A	FY17A	FY18A	FY19A	FY20A	FY21F	FY22F	FY23F
PE (x)	-10.2	-7.8	-7.0	-8.5	-17.7	-10.7	-9.4	-12.5
EV/EBITDA (x)	-18.3	-12.5	-10.4	-10.2	-20.7	-10.5	-8.1	-10.4
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FCF yield (%)	-4.7	-6.2	-8.5	-7.6	-4.5	-11.3	-10.8	-5.5
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

Profit and loss ($m)

	FY16A	FY17A	FY18A	FY19A	FY20A	FY21F	FY22F	FY23F
Sales revenue	0.0	0.0	0.0	0.0	0.0	0.7	2.3	3.1
EBITDA	-4.9	-7.2	-8.6	-8.8	-4.3	-8.6	-11.1	-8.6
Depn & amort	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EBIT	**-4.9**	**-7.2**	**-8.7**	**-8.8**	**-4.4**	**-8.6**	**-11.1**	**-8.7**
Net interest expense	-0.2	-0.2	-0.1	-0.2	-0.1	-0.4	-0.4	-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)	**-4.8**	**-7.0**	**-8.5**	**-8.6**	**-4.3**	**-8.2**	**-10.7**	**-8.2**
Abns/exts/signif	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Reported net profit	**-4.8**	**-7.0**	**-8.5**	**-8.6**	**-4.3**	**-8.2**	**-10.7**	**-8.2**

Cash flow ($m)

	FY16A	FY17A	FY18A	FY19A	FY20A	FY21F	FY22F	FY23F
EBITDA	-4.9	-7.2	-8.6	-8.8	-4.3	-8.6	-11.1	-8.6
Interest & tax	0.0	0.0	0.0	0.0	0.0	-0.4	-0.4	-0.5
Working cap/other	0.3	1.1	0.2	1.2	-0.1	-2.1	1.0	3.8
Operating cash flow	**-4.6**	**-6.1**	**-8.4**	**-7.5**	**-4.5**	**-11.0**	**-10.5**	**-5.3**
Maintenance capex	-0.1	-0.1	0.0	0.0	0.0	-0.2	-0.2	-0.2
Free cash flow	**-4.6**	**-6.2**	**-8.4**	**-7.5**	**-4.5**	**-11.2**	**-10.7**	**-5.5**
Dividends paid	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0
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	-0.5	3.4	-1.1	0.0	-1.3	0.0	0.0	0.0
Cash flow pre-financing	**-5.1**	**-2.7**	**-9.5**	**-7.5**	**-5.8**	**-11.2**	**-10.7**	**-3.5**
Funded by equity	12.4	1.0	16.7	0.0	19.1	0.0	25.0	0.0
Funded by debt	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0
Funded by cash	-7.3	1.8	-7.2	7.5	-13.3	11.2	-14.3	3.5

Balance sheet summary ($m)

	FY16A	FY17A	FY18A	FY19A	FY20A	FY21F	FY22F	FY23F
Cash	9.8	8.0	15.2	7.7	21.0	9.8	24.1	18.6
Current receivables	2.6	3.5	4.5	3.8	2.8	4.0	4.0	1.3
Current inventories	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1
Net PPE	0.1	0.1	0.1	0.1	0.1	0.3	0.5	0.7
Intangibles/capitalised	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total assets	**15.9**	**11.8**	**19.9**	**11.7**	**24.1**	**14.3**	**28.7**	**20.8**
Current payables	1.0	1.5	1.6	0.8	1.8	0.2	0.4	0.6
Total debt	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total liabilities	**1.1**	**1.7**	**1.7**	**1.0**	**2.2**	**0.5**	**0.7**	**1.0**
Shareholder equity	**14.8**	**10.1**	**18.2**	**10.7**	**21.9**	**13.7**	**28.0**	**19.8**
Total funds employed	**14.8**	**10.1**	**18.2**	**10.7**	**21.9**	**13.7**	**28.0**	**19.8**

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 2018 and be the subject of a large clinical trial in the US commencing in the same year. We estimate a US$350m sales opportunity in the major pancreatic cancer markets.

Investment thesis

We maintain our OVERWEIGHT rating and $0.40 price target on Oncosil Medical. A US FDA humanitarian clearance later this year could re-rate the stock. HDE is a niche form of approval but it offers OncoSil™ a uniformity and immediacy in market access terms that will take years to develop in Europe/AsiaPac. It also offers investors ample precedent approvals to examine as predicates. The most relevant is Boston Scientific's TheraSphere business in liver cancer which has operated for over 20 years under a HDE. There is some residual uncertainty as to the scope of Oncosil's US pivotal trial campaign (in pancreatic cancer) but all the signals point to that study being smaller than originally envisaged.

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)

Balance sheet

- As at end FY20, Oncosil had ~$21m in cash and no debt

Margin drivers

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

Board

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

Key issues/catalysts

- Country-level approvals in EMEA and AsiaPac
- FDA approval of HDE in cholangiocarcinoma
- Clinical trial execution, results and FDA approvals in pancreatic cancer
- Potential for commercial partnering interest over the next few years as sales and US pivotal trial gains momentum

Management

- Daniel Kenny (CEO)
- Karl Pechmann (CFO)
- Nigel Lange (President EMEA)
- Charles Rowland (President – US)

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

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Disclaimers and disclosures

Recommendation structure and other definitions

Definitions at wilsonsadvisory.com.au/Disclosures.

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