EQUITY RESEARCH

Company Report

Australia

Life Sciences Tools & Services

Oncosil Medical

OVERWEIGHT

February 24, 2021

Price: AUD 0.11

Bloomberg:
[OSL AU]

Market Cap:
USD 89.00 m

Outstanding Shares:
807.34 m

Six Month Avg. Daily Trading vol. (USD m): 0.36

52 week High/Low:
AUD 0.20 / AUD 0.08

1H21 STRATEGIC UPDATE: "TWO BIRDS, ONE STONE"

> We maintain our OVERWEIGHT rating on Oncosil Medical with a revised price target of $0.25. The change in leadership at Oncosil brings a new level of commitment to clinical evidence development and market access. The company's strategic update delivered a frank assessment of its near term commercial prospects in Europe, where the supporting data is encouraging but lacks statistical clout.

> Oncosil will sponsor a global clinical trial to generate comparative evidence to secure broad adoption and potential approval in USA. Importantly, the company's plans for an early humanitarian approval and market access in USA remains live, offering catalysts over the next 12 months. Success could re-rate OSL target back to $0.35 per share. Our fundamental view on OncoSilTM's asset value in pancreatic cancer treatment is consistent with prior research (FY25e asset value of ~A$1Bn). Note that our un-risked valuation of OSL is $0.71 per share.

> Committing to Level 1 evidence. Oncosil will adopt a "two birds, one stone" approach with regards to clinical evidence development this year. The company plans to sponsor a global, randomised controlled study to prove that the addition of OncoSilTM to the standard of care improves outcomes in treating unresectable, locally advanced, non-metastatic pancreatic cancer (uLAPC). The trial serves two objectives: a) secure reimbursement to adequately monetise the company's hard-won CE Mark in Europe; and b) form the basis of a Pre- market Approval (PMA) application for FDA approval. We estimate the clinical trial could recruit ~200 patients and take at least 3.5 years to complete.

> Humanitarian device exemption (HDE) in the USA a surer path to early revenue. Oncosil's HDE application to FDA has experienced COVID-related delays but is potentially deliverable this year. If successful, we anticipate US sales under this program (treating bile duct cancer) will move faster than what is achievable in Europe under CE Mark. Oncosil's European approval was based on a single-arm, uncontrolled pilot study (PanCO) and as such can only expect limited, private pay adoption. FDA HDE approvals, in contrast, are backed by US Medicare reimbursement with follow-on support by commercial payers.

IMPORTANT DISCLOSURE ON LAST PAGE

WILSONS
Equity Research

Date
24 February 2021

Theme
Company Update

Company
Oncosil Medical (OSL)

1H21 Strategic Update: "Two birds, one stone"

Recommendation	**OVERWEIGHT**
12-mth target price (AUD)	**$0.25**
Share price @ 23-Feb-21 (AUD)	$0.11
Forecast 12-mth capital return	127.3%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	**127.3%**
Market cap	$89m
Enterprise value	$71m
Shares on issue	807m
Sold short	
ASX 300 weight	n/a
Median turnover/day	$0.2m

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Key points

Committing to Level 1 evidence. Oncosil will adopt a "two birds, one stone" approach with regards to clinical evidence development this year. The company plans to sponsor a global, randomised controlled study to prove that the addition of OncoSil™ to the standard of care improves outcomes in treating unresectable, locally advanced, non-metastatic pancreatic cancer (uLAPC). The trial serves two objectives: a) secure reimbursement to adequately monetise the company's hard-won CE Mark in Europe; and b) form the basis of a Pre-market Approval (PMA) application for FDA approval. We estimate the clinical trial could recruit ~200 patients and take at least 3.5 years to complete.

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Lower 12-month price target but fundamental view on asset value consistent with prior Research With a pivotal trial now the centrepiece of how value is realised, a real options valuation (ROV) is a more appropriate way to assess value. We have retained the same patient-based, bottom-up approach to assessing the OncoSil™ TAM and forecast an FY25e asset value of ~A$1Bn. Our new price target of $0.25 per share controls for two risks: a) HDE approval'; and b) FDA approving Oncosil's pivotal trial design. We assess that both are deliverable over the next 12 months and could support a price target up to $0.35 per share (further 40% upside).

Risks and catalysts described on p.5 of this report.

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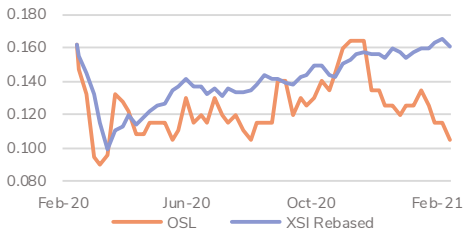
12-mth price performance ($)



	1-mth	6-mth	12-mth
Abs return (%)	-22.2	-4.5	-36.4
Rel return (%)	-23.5	-18.8	-36.0

Earnings forecasts

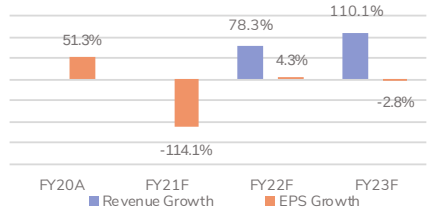
Year-end June (AUD)	FY19A	FY20A	FY21F	FY22F	FY23F
NPAT rep ($m)	-8.6	-4.3	-10.6	-11.6	-12.1
NPAT norm ($m)	-8.6	-4.3	-10.6	-11.6	-12.1
Consensus NPAT ($m)			-6.3	-8.6	-5.2
EPS norm (cps)	-1.4	-0.6	-1.4	-1.3	-1.4
EPS growth (%)	17.4	52.3	-114.1	4.3	-2.8
P/E norm (x)	-8.1	-16.9	-7.9	-8.3	-8.0
EV/EBITDA (x)	-8.1	-16.4	-6.7	-5.9	-5.7
FCF yield (%)	-8.5	-5.0	-10.7	-13.2	-9.8
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

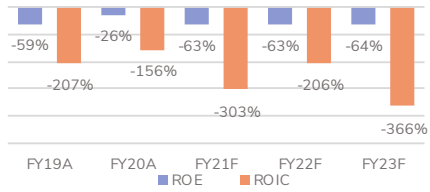
Key changes

		03-Sep	After	Var %
NPAT:	**FY21F**	-8.2	-10.6	N/A
norm	**FY22F**	-10.7	-11.6	N/A
($m)	**FY23F**	-8.2	-12.1	N/A
EPS:	**FY21F**	-1.1	-1.4	N/A
norm	**FY22F**	-1.2	-1.3	N/A
(cps)	**FY23F**	-0.9	-1.4	N/A
DPS:	**FY21F**	0.0	0.0	0.0%
(cps)	**FY22F**	0.0	0.0	0.0%
	FY23F	0.0	0.0	0.0%
Price target:		0.40	0.25	-37.5%
Rating:		O/W	O/W	

Growth rates

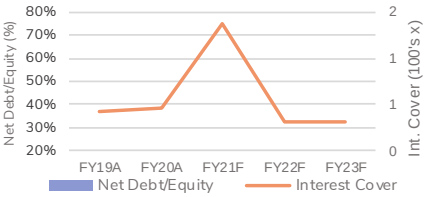


Returns

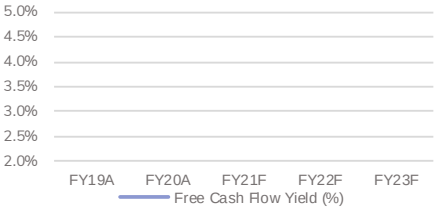


Margin trends

Solvency



Free cash flow yield



Interims ($m)

	1H20A	2H20A	1H21A	2H21E
Sales revenue	0.0	0.0	0.1	0.1
EBITDA	-3.4	-0.9	-4.6	-6.0
EBIT	-3.5	-0.9	-4.7	-6.0
Net profit	**-3.4**	**-0.9**	**-4.7**	**-5.9**
Norm EPS	**-0.5**	**-0.2**	**-0.6**	**-0.7**
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

	FY16A	FY17A	FY18A	FY19A	FY20A	FY21F	FY22F	FY23F
Revenue Growth (%)							78.3	110.1
EBIT Growth (%)	62.5	46.9	20.0	1.0	-50.3	145.7	11.8	4.8
NPAT Growth (%)	65.6	47.1	21.7	0.3	-50.3	149.3	9.1	4.7
EPS Growth (%)	**38.7**	**31.4**	**11.5**	**-17.4**	**-52.3**	**114.1**	**-4.3**	**2.8**
EBIT / Sales (%)						-5,647.4	-3,541.1	-1,766.0
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**	**-59.1**	**-63.3**	**-63.9**
ROE (%)	**-43.8**	**-56.3**	**-60.4**	**-59.4**	**-26.2**	**-63.2**	**-62.9**	**-63.6**

Financial ratios

	FY16A	FY17A	FY18A	FY19A	FY20A	FY21F	FY22F	FY23F
PE (x)	-9.3	-7.1	-6.4	-7.7	-16.2	-7.6	-7.9	-7.7
EV/EBITDA (x)	-14.5	-9.9	-8.2	-8.1	-16.4	-6.7	-5.9	-5.7
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FCF yield (%)	-5.2	-6.9	-9.5	-8.5	-5.0	-10.7	-13.2	-9.8
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

Profit and loss ($m)

	FY16A	FY17A	FY18A	FY19A	FY20A	FY21F	FY22F	FY23F
Sales revenue	0.0	0.0	0.0	0.0	0.0	0.2	0.3	0.7
EBITDA	-4.9	-7.2	-8.6	-8.8	-4.3	-10.6	-11.9	-12.5
Depn & amort	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0
EBIT	**-4.9**	**-7.2**	**-8.7**	**-8.8**	**-4.4**	**-10.7**	**-12.0**	**-12.5**
Net interest expense	-0.2	-0.2	-0.1	-0.2	-0.1	-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)	**-4.8**	**-7.0**	**-8.5**	**-8.6**	**-4.3**	**-10.6**	**-11.6**	**-12.1**
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**	**-10.6**	**-11.6**	**-12.1**

Cash flow ($m)

	FY16A	FY17A	FY18A	FY19A	FY20A	FY21F	FY22F	FY23F
EBITDA	-4.9	-7.2	-8.6	-8.8	-4.3	-10.6	-11.9	-12.5
Interest & tax	0.0	0.0	0.0	0.0	0.0	-0.1	-0.4	-0.4
Working cap/other	0.3	1.1	0.2	1.2	-0.1	1.3	0.8	4.4
Operating cash flow	**-4.6**	**-6.1**	**-8.4**	**-7.5**	**-4.5**	**-9.4**	**-11.5**	**-8.5**
Maintenance capex	-0.1	-0.1	0.0	0.0	0.0	-0.1	-0.2	-0.2
Free cash flow	**-4.6**	**-6.2**	**-8.4**	**-7.5**	**-4.5**	**-9.5**	**-11.7**	**-8.7**
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**	**-9.5**	**-11.7**	**-6.7**
Funded by equity	12.4	1.0	16.7	0.0	19.1	0.3	25.0	0.0
Funded by debt	0.0	0.0	0.0	0.1	0.0	-0.1	0.0	0.0
Funded by cash	-7.3	1.8	-7.2	7.5	-13.3	9.3	-13.3	6.7

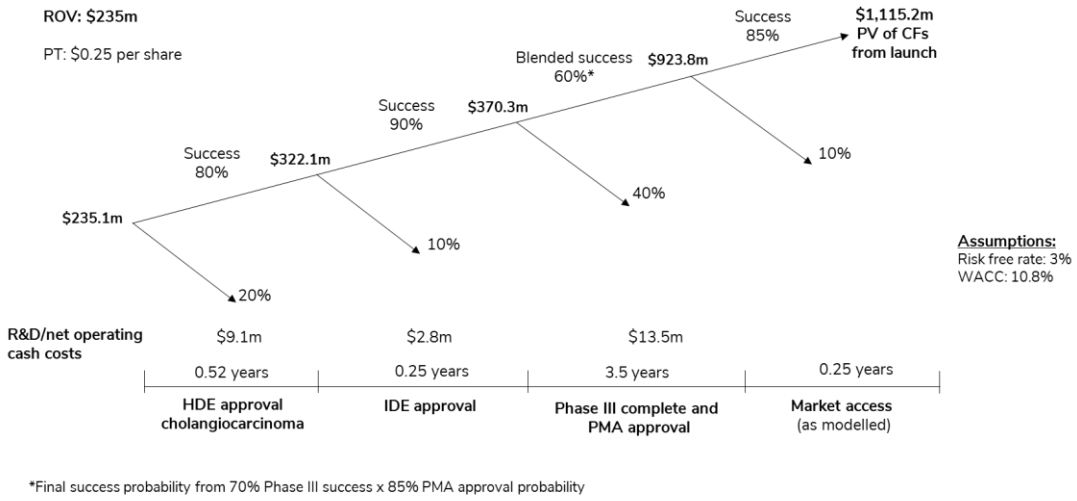
Balance sheet summary ($m)

	FY16A	FY17A	FY18A	FY19A	FY20A	FY21F	FY22F	FY23F
Cash	9.8	8.0	15.2	7.7	21.0	7.7	21.0	12.3
Current receivables	2.6	3.5	4.5	3.8	2.8	4.0	4.0	0.5
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	0.1	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**	**12.1**	**25.6**	**13.6**
Current payables	1.0	1.5	1.6	0.8	1.8	0.0	0.1	0.2
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**	**0.4**	**0.5**	**0.6**
Shareholder equity	**14.8**	**10.1**	**18.2**	**10.7**	**21.9**	**11.7**	**25.1**	**13.0**
Total funds employed	**14.8**	**10.1**	**18.2**	**10.7**	**21.9**	**11.7**	**25.1**	**13.0**

Valuation

Our revised ROV approach leaves us with a risked 12-month price target of $0.25 for Oncosil. *Unrisked PT = $0.71*

Figure 1. Real Options Valuation of Oncosil's market opportunity



*Final success probability from 70% Phase III success x 85% PMA approval probability

Source: Wilsons

We have risked key approval stages ahead of broad market access. Key stages reflect key points of risk and binary outcomes toward end market access with reimbursement from key governments. We view HDE approval as the first stage for the US bile duct opportunity later this CY. Followed by an IDE approval as the first step toward being allowed to conduct a global multi-centre pivotal trial which Oncosil would receive from the FDA. Following this, is trial execution which we anticipate to take ~3.5 years, combined with a marketing (PMA) approval. This is based on a hypothesized design including ~200 patients, a ~2+ year recruitment window with a 6 month timeline to the primary endpoint measure (resection rate), followed by top-line data review, preparation of the PMA application, subsequent approval and near term market access. (See Figure 1).

Cash. Oncosil's current cash burn was described as $3M per quarter during last week's update. At end 1H21 Oncosil had ~$18M cash reserves leaving them 18 months runway (to end 2H22) assuming no uptick in Opex over this period. We anticipate increased R&D investment over this period as well as SG&A whilst they attempt to get more private payer sales in UK and make HDE sales in the US following approval. We maintain our forecast for a A$25M capital raise in FY22 to support pivotal trial activities.

Operational update

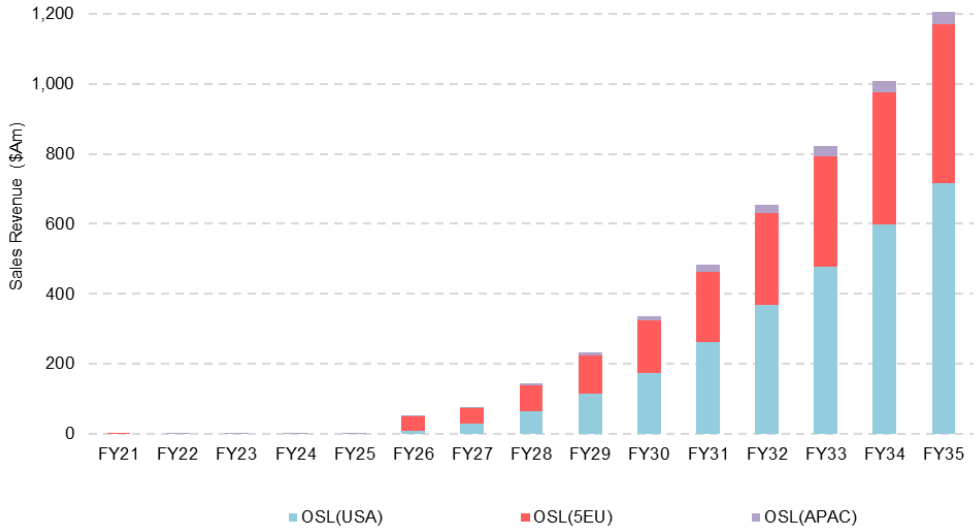
Manufacturing capacity in place. The manufacturing capabilities are in place to supply the Oncosil device as they ramp sales in the next 3 years, with the CEO confirming supply chains within both the US and EU as being robust and able to weather COVID interruptions. As a reminder, the device is manufactured in Germany by their partner (Eckert & Zeigler) with the radioactive targets irradiated here in Australia in the Lucas Heights facility before being shipped out to EU and US markets.

Near term revenue focus. Oncosil confirmed their focus on near term revenues from the UK private payers with a sales team focused on localising marketing in catchment areas identified to have favourable private pay demographics (i.e. private insurance policies, private hospitals). We view this as a positive initial focus for Oncosil in the EU region until data to support reimbursement is generated. Keeping in mind that the private payer market is <10% of addressable market in EU (much less in some regions).

Changes to Forecasts

We maintain our assumptions regarding the pancreatic cancer market and the positioning of the Oncosil device as being transformative in this market. We simply amend our EU market entry ramp to account for a small number of private payers in UK/SUI and move major market access (EU/US) back to FY26 to account for the upcoming global pivotal PMA trial which has now been confirmed as the definitive path toward European reimbursement, simultaneous to US market entry. See Figure 2.

Figure 2. Revenue forecasts for Oncosil launch into major EU5 and US markets following pivotal trial



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™ 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 price target of $0.25. The change in leadership at Oncosil brings a new level of commitment to clinical evidence development and market access. The company's strategic update delivered a frank assessment of its near term commercial prospects in Europe, where the supporting data is encouraging but lacks statistical clout. Oncosil will sponsor a global clinical trial to generate comparative evidence to secure broad adoption and potential approval in USA. Importantly, the company's plans for an early humanitarian approval and market access in USA remains live, offering catalysts over the next 12 months. Success could re-rate OSL target back to $0.35 per share. Our fundamental view on OncoSilTM's asset value in pancreatic cancer treatment is consistent with prior research (FY25e asset value of ~A$1Bn). Note that our un-risked valuation of OSL is $0.71 per share..

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 1H21, Oncosil had ~$18m 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)

Nigel Lange (Managing Director)

Dr Roger Aston (Non-Executive Director)

Dr Martin Cross (Non-Executive Director)

Michael Bassett (Non-Executive Director)

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)

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)

Michael Warrener (Sales and Marketing Director)

Nicole Wilson (VP Regulatory Affairs and Quality)

Charles Rowland (President – US Operations)

Olaf Michaelsen (Director- Access Reimbursement, Economics, Assessment)

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.

Contact details

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Web: www.oncosil.com.au

Disclaimers and disclosures

Recommendation structure and other definitions

Definitions at wilsonsadvisory.com.au/Disclosures.

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