

BUY: Hanging in there for European approval

We maintain our BUY rating with a revised price target of \$0.38 per share. US FDA's positive opinion on the safety of the OncoSil™ medical device means the company can confidently work towards an approval-directed clinical trial in USA. It also lends important validation to the lengthy approval process in Europe, which is close to a decision. We assess that the Europeans will approve OncoSil™ and it will attract early demand with both public and private funding. OncoSil's device offers clear advantages over standard radiotherapy techniques – delivering a decisive dose of radiation to pancreatic tumours in a single procedure with good safety.

Key points

1H19 result snapshot. Oncosil reported a 1H19 loss of \$5.1m which compared well with our forecast of \$5.4m. Cash position was also slightly ahead of our model at \$13m. Cash burn has moderated with the PanCO clinical trial coming to a close and the company preparing for its US pivotal trial campaign in 2020.

Progress: a) US FDA adopted a positive opinion on safety and this allows work towards a pivotal, approval-directed trial in USA. Our statistical calculations suggest a trial size of ~150-175 pts may suffice, whereas previous trial planning indicated >300pts. Expect FDA to define this pathway in 2019 and for Oncosil to commence trial enrolment in 2020. b) ongoing frustration with a long CE Mark review should resolve late this quarter – allowing commercial launches in Europe and eventually Singapore and Australia. Final negotiations in these situations often centre on post-approval commitments and proposed label restrictions, both of which are routine with a first-in-class medical device of this kind. c) the OncoSil™ device should attract early demand given its surprisingly good results in terms of down-staging previously inoperable tumours to curative surgery – OncoSil's market development work with IQVIA has identified pockets of public funding but a cash-pay market may also develop given the very poor prognosis attached to inoperable pancreatic cancer. d) Oncosil has validated manufacturing and logistics in place to service initial demand once that crucial CE Mark and subsequent EU marketing authorisations come through.

Forecasts. We have nominal sales revenue forecasts that we'll sharpen on European approval. Our earnings changes here relate only to the phasing of clinical trial R&D expenses over the forecast period.

Valuation. Our 12-month target price of \$0.38 is down 10% owing to changes to our project financing assumptions, which are a function of clinical trial design timing and capital.

Risks and catalysts

Risks: a) product safety; b) clinical trial risks; c) funding risks; d) competition; e) lack of earnings. **Catalysts:** a) positive regulatory decisions; b) commercial partnerships; c) new product launches; d) sales traction; e) M&A.

Earnings forecasts					
Year-end June (AUD)	FY17A	FY18A	FY19F	FY20F	FY21F
NPAT rep (\$m)	-7.0	-8.5	-9.2	-8.1	-8.9
NPAT norm (\$m)	-7.0	-8.5	-9.2	-8.1	-8.9
Consensus NPAT (\$m)			-8.9	-7.9	-7.2
EPS norm (cps)	-1.5	-1.6	-1.5	-1.2	-1.3
EPS growth (%)	-31.4	-11.5	11.2	19.7	-7.0
P/E norm (x)	-11.2	-10.0	-11.3	-14.0	-13.1
EV/EBITDA (x)	-13.4	-11.2	-10.2	-11.8	-10.5
FCF yield (%)	-5.9	-8.1	-7.3	-9.3	-9.3
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

Wilsons Equity Research

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Recommendation	BUY
12-mth target price (AUD)	\$0.38
Share price @ 19-Feb-19 (AUD)	\$0.17
Forecast 12-mth capital return	133.2%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	133.2%

Market cap	\$104m
Enterprise value	\$96m
Shares on issue	631m
Sold short	
ASX 300 weight	n/a
Median turnover/day	\$0.1m

Shane Storey

shane.storey@wilsonsadvisory.com.au
Tel. +61 7 3212 1351

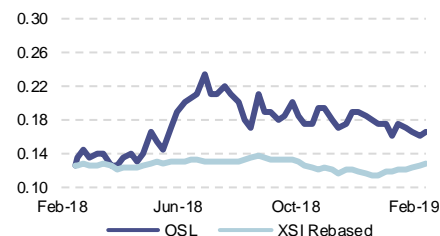
Elyse Shapiro

elyse.shapiro@wilsonsadvisory.com.au
Tel. +61 3 9640 3864



FUNDAMENTAL
INSIGHTS

12-mth price performance (\$)

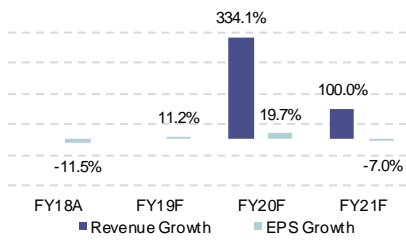


	1-mth	6-mth	12-mth
Abs return (%)	-2.9	-8.3	32.0
Rel return (%)	-8.8	-3.9	30.2

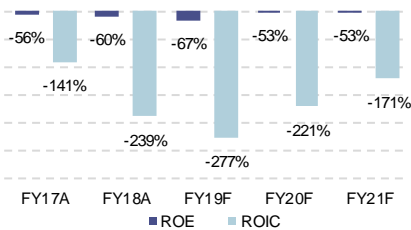
Key changes

		30-Oct	After	Var %
NPAT:	FY19F	-11.4	-9.2	N/A
norm	FY20F	-7.7	-8.1	N/A
(\$m)	FY21F	-7.2	-8.9	N/A
EPS:	FY19F	-1.9	-1.5	N/A
norm	FY20F	-1.3	-1.2	N/A
(cps)	FY21F	-1.2	-1.3	N/A
DPS:	FY19F	0.0	0.0	0.0%
(cps)	FY20F	0.0	0.0	0.0%
	FY21F	0.0	0.0	0.0%
Price target:		0.43	0.38	-10.8%
Rating:		BUY	BUY	

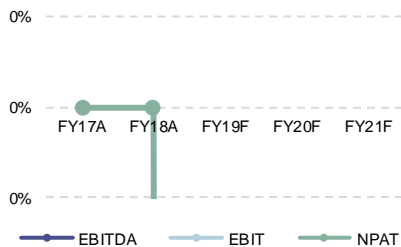
Growth rates



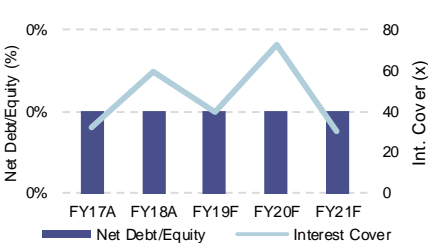
Returns



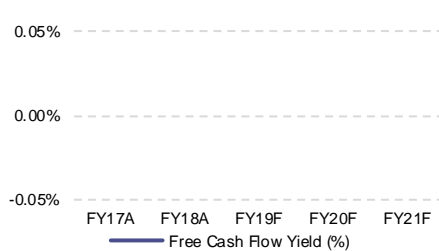
Margin trends



Solvency



Free cash flow yield



Interims (\$m)

	1H18A	2H18A	1H19A	2H19E
Sales revenue	0.0	0.0	0.0	0.2
EBITDA	-4.6	-4.1	-5.2	-4.2
EBIT	-4.6	-4.1	-5.3	-4.2
Net profit	-4.5	-4.0	-5.1	-4.1
Norm EPS	-0.8	-0.8	-0.8	-0.6
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

	FY14A	FY15A	FY16A	FY17A	FY18A	FY19F	FY20F	FY21F
Revenue Growth (%)							334.1	100.0
EBIT Growth (%)	382.6	-35.9	62.5	46.9	20.0	8.7	-12.8	12.4
NPAT Growth (%)	379.7	-31.7	65.6	47.1	21.7	7.8	-11.9	10.1
EPS Growth (%)	139.6	-40.4	38.7	31.4	11.5	-11.2	-19.7	7.0
EBIT / Sales (%)						-5,815.4	-1,167.4	-656.0
Tax Rate (%)	6.9	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ROA (%)	-51.0	-30.8	-42.3	-52.3	-54.8	-61.9	-50.9	-53.3
ROE (%)	-46.3	-30.1	-43.8	-56.3	-60.4	-66.7	-52.7	-53.0

Financial ratios

	FY14A	FY15A	FY16A	FY17A	FY18A	FY19F	FY20F	FY21F
PE (x)	-12.1	-20.4	-14.7	-11.2	-10.0	-11.3	-14.0	-13.1
EV/EBITDA (x)	-20.4	-31.9	-19.7	-13.4	-11.2	-10.2	-11.8	-10.5
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FCF yield (%)	-6.1	-0.2	-4.4	-5.9	-8.1	-7.3	-9.3	-9.3
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)

	FY14A	FY15A	FY16A	FY17A	FY18A	FY19F	FY20F	FY21F
Sales revenue	0.0	0.0	0.0	0.0	0.0	0.2	0.7	1.4
EBITDA	-4.7	-3.0	-4.9	-7.2	-8.6	-9.4	-8.2	-9.2
Depn & amort	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EBIT	-4.7	-3.0	-4.9	-7.2	-8.7	-9.4	-8.2	-9.2
Net interest expense	-0.2	-0.2	-0.2	-0.2	-0.1	-0.2	-0.1	-0.3
Tax	-0.3	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)	-4.2	-2.9	-4.8	-7.0	-8.5	-9.2	-8.1	-8.9
Abns/exts/signif	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Reported net profit	-4.2	-2.9	-4.8	-7.0	-8.5	-9.2	-8.1	-8.9

Cash flow (\$m)

	FY14A	FY15A	FY16A	FY17A	FY18A	FY19F	FY20F	FY21F
EBITDA	-4.7	-3.0	-4.9	-7.2	-8.6	-9.4	-8.2	-9.2
Interest & tax	-0.2	2.8	0.0	0.0	0.0	-0.1	-0.1	-0.3
Working cap/other	-1.4	0.1	0.3	1.1	0.2	2.0	-1.2	0.0
Operating cash flow	-6.4	-0.2	-4.6	-6.1	-8.4	-7.5	-9.5	-9.5
Maintenance capex	0.0	0.0	-0.1	-0.1	0.0	-0.1	-0.2	-0.2
Free cash flow	-6.4	-0.2	-4.6	-6.2	-8.4	-7.6	-9.7	-9.7
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	-4.7	0.0	-0.5	3.4	-1.1	0.0	0.0	0.0
Cash flow pre-financing	-11.1	-0.2	-5.1	-2.7	-9.5	-7.6	-9.7	-9.7
Funded by equity	10.3	0.0	12.4	1.0	16.7	0.0	20.0	0.0
Funded by debt	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0
Funded by cash	0.8	0.2	-7.3	1.8	-7.2	7.6	-10.3	9.7

Balance sheet summary (\$m)

	FY14A	FY15A	FY16A	FY17A	FY18A	FY19F	FY20F	FY21F
Cash	2.7	2.5	9.8	8.0	15.2	7.6	17.9	8.2
Current receivables	0.1	0.1	2.6	3.5	4.5	2.6	3.2	4.0
Current inventories	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1
Net PPE	0.0	0.1	0.1	0.1	0.1	0.2	0.3	0.5
Intangibles/capitalised	2.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total assets	12.3	7.4	15.9	11.8	19.9	10.6	21.7	13.0
Current payables	0.0	0.2	1.0	1.5	1.6	1.0	0.2	0.4
Total debt	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total liabilities	0.1	0.4	1.1	1.7	1.7	1.2	0.4	0.6
Shareholder equity	12.2	7.0	14.8	10.1	18.2	9.5	21.3	12.4
Total funds employed	12.2	7.0	14.8	10.1	18.2	9.5	21.3	12.4



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 2019 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 maintain our BUY rating with a revised price target of \$0.38 per share. US FDA's positive opinion on the safety of the OncoSil™ medical device means the company can confidently work towards an approval-directed clinical trial in USA. It also lends important validation to the lengthy approval process in Europe, which is close to a decision. We assess that the Europeans will approve OncoSil™ and it will attract early demand with both public and private funding. OncoSil's device offers clear advantages over standard radiotherapy techniques – delivering a decisive dose of radiation to pancreatic tumours in a single procedure with good safety.

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)

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

- 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

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

Balance sheet

- As at end 1Q19, Oncosil had ~\$16m in cash and no debt.

Board

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

Management

- Daniel Kenny (CEO)
- Tom Milicevic (CFO)
- Dr Ash Soman (CMO)
- Charles Rowland (President – US Operations)

Contact details

Address: Suite 402, Level 4, 50 Berry Street, North Sydney, NSW 2060

Phone: +61 2 9223 3344

Web: www.oncosil.com.au



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Recommendation structure and other definitions

Definitions at wilsonsadvisory.com.au/Disclosures.

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For more information please phone: 1300 655 015 or email: publications@wilsonsadvisory.com.au

