

First patient enrolled in the OncoPac-1 trial

We maintain our BUY rating with a revised price target of 38cps (\$2.00 un-risked on a three-year view). Oncosil Medical has enrolled the first subject in its OncoPac-1 clinical trial. This clinical trial seeks to establish OncoSil™ as a first-line therapy for patients diagnosed with locally advanced pancreatic cancer (LAPC). LAPC is a swiftly lethal disease in which conventional radiotherapy struggles for significance, taking too long to administer and adding too much toxicity over chemotherapy. OncoSil™ is an old idea in some ways but the chance of being able to deliver a tumour-killing dose of radiation in one procedure with good safety has seen major oncology centres join the queue to get their LAPC patients into OncoPac-1. Once the trial's "pilot" phase is over and it launches nationally in the USA, we think the stock will capture some much deserved investor attention.

Key points

OncoPac-1 trial enrolls its first patient. To the best of our knowledge, Oncosil's OncoPac-1 clinical trial is the largest "Level 1 evidence" generating trial of its kind to be attempted in pancreatic cancer. We have been impressed by the initial reaction from international treatment centres seeking to participate. We understand their enthusiasm because the role of chemoradiation in pancreatic cancer remains highly controversial. Upfront, conventional radiotherapy does not appear to be effective and it adds unacceptable toxicity over a long treatment period (up to six weeks). OncoSil™'s concept of a tumour-killing dose, delivered in one procedure with good safety and minimal incremental toxicity, remains a compelling medical device idea.

Valuation. Our \$0.38/share price target is set using risk-adjusted DCF. Our underlying sales forecasts for OncoSil™ map reasonably well against the net sales achieved by Sirtex Medical's SIR-Spheres in its first decade post major approvals. SIR-Spheres is a good predicate for OncoSil™ although the latter has two putative advantages: a) an earlier EU marketing clearance; and b) a superior marketing label at the time of US launch (assuming OncoPac-1 trial success and regulatory clearance). Oncosil should be able to access "first line" LAPC patients immediately following its product's FDA approval, unlike Sirtex which was only able to access patients that had failed multiple rounds of prior chemotherapy (smaller eligible treatment population).

Risks and catalysts

Catalysts: a) obtaining CE Mark; b) IDE trial progress; c) EU marketing approval and first sales; d) board renewal. **Risks:** a) access to development capital; b) clinical trial risks; c) regulatory risks; d) product safety/quality/logistics risks; e) volatile sentiment in early stage life science and biotechnology sector.

Recommendation

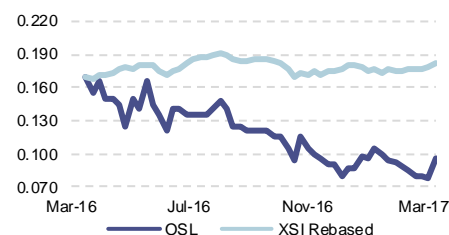
12-mth target price (AUD)	BUY \$0.38
Share price @ 31-Mar-17 (AUD)	\$0.10
Forecast 12-mth capital return	300.5%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	300.5%

Market cap	\$45m
Enterprise value	\$39m
Shares on issue	468m
Sold short	
ASX 300 weight	n/a
Median turnover/day	\$0.0m

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12-mth price performance (\$)



	1-mth	6-mth	12-mth
Abs return (%)	10.5	-20.8	-44.1
Rel return (%)	7.7	-18.4	-50.9

Key changes

		25-Feb	After	Var %
NPAT:	FY17F	-7.7	-8.8	N/A
norm	FY18F	-12.6	-12.7	N/A
(\$m)	FY19F	-10.5	-11.5	N/A
EPS:	FY17F	-1.5	-1.7	N/A
norm	FY18F	-2.1	-2.2	N/A
(cps)	FY19F	-1.6	-1.9	N/A
DPS:	FY17F	0.0	0.0	0.0%
(cps)	FY18F	0.0	0.0	0.0%
	FY19F	0.0	0.0	0.0%
Price target:		0.40	0.38	-6.0%
Rating:		BUY	BUY	

Earnings forecasts

Year-end June (AUD)	FY15A	FY16A	FY17F	FY18F	FY19F
NPAT rep (\$m)	-2.9	-4.8	-8.8	-12.7	-11.5
NPAT norm (\$m)	-2.9	-4.8	-8.8	-12.7	-11.5
Consensus NPAT (\$m)			-7.5	-11.3	10.3
EPS norm (cps)	-0.8	-1.2	-1.7	-2.2	-1.9
EPS growth (%)	40.4	-53.4	-40.6	-25.3	14.9
P/E norm (x)	-11.7	-7.6	-5.4	-4.3	-5.1
EV/EBITDA (x)	-12.8	-7.9	-4.3	-3.0	-3.3
FCF yield (%)	-0.5	-10.4	-14.8	-29.8	-26.6
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 Research

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Price target		
	Valuation	Price target
DCF methodology		
WACC estimate (%)	14.5	
Terminal growth rate (%)	3.5	
PV of forecast FCFs (\$m)	8.0	
PV of terminal value (\$m)	218.5	
Enterprise value (\$m)	226.5	
Net debt (cash) (\$m)	-5.8	
Equity value (\$m)	232.3	

Price target (\$/share)	0.38
Un-risked 3-yr valuation (\$/share)	2.20

Interims (\$m)				
Half-year (AUD)	Dec 15	Jun 16	Dec 16	Jun 17
	1HA	2HA	1HE	2HE
Sales revenue	0.0	0.0	0.9	0.0
EBITDA	-1.8	-3.1	-3.2	-5.8
EBIT	-1.8	-3.1	-3.2	-5.8
Net profit	-1.8	-3.0	-3.1	-5.7
Norm EPS	-0.5	-0.7	-0.7	-1.0
EBIT/sales (%)				
Dividend (c)	0.0	0.0	0.0	0.0
Franking (%)	0.0	0.0	0.0	0.0

Financial stability			
Year-end June (AUD)	FY16A	FY17F	FY18F
Net debt	-9.8	-5.8	-2.5
Net debt/equity (%)	<0	<0	<0
Net debt/EV (%)	<0	<0	<0
Current ratio (x)	14.6	15.6	8.7
Interest cover (x)	31.2	39.9	85.3
Adj cash int cover (x)	30.3	30.2	89.1
Debt/cash flow (x)	0.0	0.0	0.0
Net debt (cash)/share (\$)	<0	<0	0.0
NTA/share (\$)	0.0	0.0	0.0
Book value/share (\$)	0.0	0.0	0.0
Payout ratio (%)	0	0	0
Adj payout ratio (%)	0	0	0

EPS reconciliation (\$m)				
	FY16A		FY17F	
	Rep	Norm	Rep	Norm
Sales revenue	0	0	1	1
EBIT	-4.9	-4.9	-9.0	-9.0
Net profit	-4.8	-4.8	-8.8	-8.8
Notional earn	0.0	0.0	0.0	0.0
Pref/conv div	0.0	0.0	0.0	0.0
Profit for EPS	-4.8	-4.8	-8.8	-8.8
Diluted shrs (m)	383	383	502	502
Diluted EPS (c)	-1.2	-1.2	-1.7	-1.7

Returns				
	FY16A	FY17F	FY18F	FY19F
ROE (%)	-44	-82	-238	-359
ROIC (%)	-73	-213	-768	-507
Incremental ROE	-143	>999	72	-54
Incremental ROIC	60	161	151	196

Key assumptions									
Year-end June (AUD)	FY13A	FY14A	FY15A	FY16A	FY17F	FY18F	FY19F	FY20F	
Revenue growth (%)	-100.0					-68.0	383.1	139.8	
EBIT growth (%)	-104.9	382.6	-35.9	62.5	82.8	42.7	-9.5	-45.4	
NPAT growth (%)	-105.1	379.7	-31.7	65.6	84.2	44.7	-9.1	-46.1	
EPS growth (%)	-101.9	139.6	-40.4	53.4	40.6	25.3	-14.9	-46.1	
EBIT/sales (%)									
Tax rate (%)	0.0	6.9	0.0	0.0	0.0	0.0	0.0	0.0	
ROA (%)	-15.7	-38.5	-40.9	-46.4	-120.7	-203.7	-131.4	-53.4	
ROE (%)	-14.5	-34.7	-41.4	-47.7	-125.6	-386.9	2,139.2	189.3	

Profit and loss (\$m)									
Year-end June (AUD)	FY13A	FY14A	FY15A	FY16A	FY17F	FY18F	FY19F	FY20F	
Sales revenue	0.0	0.0	0.0	0.0	0.9	0.3	1.4	3.5	
EBITDA	-1.0	-4.7	-3.0	-4.9	-9.0	-12.8	-11.6	-6.3	
Depn & amort	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.1	
EBIT	-1.0	-4.7	-3.0	-4.9	-9.0	-12.9	-11.6	-6.4	
Net interest expense	-0.1	-0.2	-0.2	-0.2	-0.2	-0.2	-0.1	-0.1	
Tax	0.0	-0.3	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)	-0.9	-4.2	-2.9	-4.8	-8.8	-12.7	-11.5	-6.2	
Abns/exts/signif	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Reported net profit	-0.9	-4.2	-2.9	-4.8	-8.8	-12.7	-11.5	-6.2	

Cash flow (\$m)									
Year-end June (AUD)	FY13A	FY14A	FY15A	FY16A	FY17F	FY18F	FY19F	FY20F	
EBITDA	-1.0	-4.7	-3.0	-4.9	-9.0	-12.8	-11.6	-6.3	
Interest & tax	-0.1	-0.2	2.8	0.0	-0.1	-0.2	-0.1	-0.1	
Working cap/other	0.6	-1.4	0.1	0.3	2.6	-0.1	0.0	15.0	
Operating cash flow	-0.5	-6.4	-0.2	-4.6	-6.5	-13.1	-11.6	8.6	
Maintenance capex	0.0	0.0	0.0	-0.1	-0.1	-0.2	-0.2	-0.2	
Free cash flow	-0.5	-6.4	-0.2	-4.6	-6.6	-13.3	-11.8	8.4	
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	
Other inv flows	-0.2	-4.7	0.0	-0.5	2.6	0.0	0.0	0.0	
Cash flow pre-financing	-0.7	-11.1	-0.2	-5.1	-4.0	-13.3	-11.8	8.4	
Funded by equity	1.8	10.3	0.0	12.4	0.0	10.0	10.0	0.0	
Funded by debt	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Funded by cash	-1.1	0.8	0.2	-7.3	4.0	3.3	1.8	-8.4	

Balance sheet summary (\$m)									
Year-end June (AUD)	FY13A	FY14A	FY15A	FY16A	FY17F	FY18F	FY19F	FY20F	
Cash	3.5	2.7	2.5	9.8	5.8	2.5	0.7	9.1	
Current receivables	0.0	0.1	0.1	2.6	0.2	0.7	0.8	1.2	
Current inventories	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	
Net PPE	0.0	0.0	0.1	0.1	0.2	0.3	0.5	0.6	
Investments	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Intangibles/capitalised	2.6	2.6	0.0	0.0	0.0	0.0	0.0	0.0	
Other	0.0	6.7	4.8	3.4	0.9	0.9	0.9	0.9	
Total assets	6.2	12.3	7.4	15.9	7.1	4.5	2.9	11.9	
Current payables	0.1	0.0	0.2	1.0	0.3	0.4	0.4	0.6	
Total debt	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Other liabilities	0.1	0.1	0.3	0.1	0.1	0.1	0.1	14.6	
Total liabilities	0.2	0.1	0.4	1.1	0.5	0.5	0.5	15.2	
Minorities/convertibles	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Shareholder equity	6.1	12.2	7.0	14.8	6.7	4.0	2.4	-3.3	
Total funds employed	6.1	12.2	7.0	14.8	6.7	4.0	2.4	-3.3	

Oncosil Medical's OncoPac-1 clinical trial begins

Investment thesis

Oncosil Medical is an Australian medical device company developing an implantable, radioactive treatment for addressing inoperable pancreatic and liver cancers. The OncoSil™ product concept is to safely administer a radiation dose large enough to destroy a significant part of the primary tumour mass in a single procedure, with limited toxicity. This treatment outcome is not possible with conventional, fractionated radiotherapy techniques. We think OncoSil™ can change clinical practice because it offers a potential solution to the number one problem reported by medical oncologists who make the pancreas their clinical focus: the ability to “de-escalate” aggressive primary tumours that are treated with chemotherapy agents. Oncosil's product has been tested in small, uncontrolled studies in two tumour settings, with encouraging results. **Last week, the company commenced enrolment of what is planned to become a large, randomised, controlled clinical trial (OncoPac-1), which is designed to secure marketing approval for this product in the USA.**

Valuation and catalysts

- **We maintain our BUY rating with a revised price target of 38cps.** Unlocking our “un-risked” valuation of ~\$2.00 per share (over the next three years) depends on the following outcomes.
- **Timely enrolment of OncoPac-1 trial “run-in cohorts”.** OncoPac-1 has just begun and is in a pilot phase from two perspectives. The FDA will assess data collected from the first 20 US subjects from 5 centres before allowing Oncosil to expand into the full-scale 300 subject “pivotal” trial phase. The European regulators also want to see data from a 20-subject cohort before they will consider granting OncoSil™ a CE Mark (potentially enabling first commercial sales).
- **Global trial-site engagement.** We have been impressed by the initial reaction from the international pancreatic cancer community and understand that Oncosil has developed a pipeline of influential cancer centres to participate in the OncoPac-1 campaign. To the best of our knowledge, OncoPac-1 will be the largest “Level 1 evidence” clinical trial ever conducted for endoscope-assisted brachytherapy in pancreatic cancer.
- **Funding.** Oncosil is likely to require further equity capital to complete its OncoPac-1 trial. The quantum, price and timing of new equity issues are important variables in assessing company valuation in per share terms.
- **Clinical performance.** Our assessment of the proposed OncoPac-1 is very positive although the campaign will take years to complete. The trial will provide a clear answer to an important clinical question and support our OncoSil™ sales forecasts and valuation.

Risks

- **Clinical trial risks.** The failure to show a clean signal in clinical trials can lead to years of delay. Trials can fail on account of the product not being good enough, or through poor trial design and execution.
- **Early sales may disappoint through lack of evidence.** Sales in Europe and APAC (pending CE Mark and other approvals) may be very modest. Although trials to date have recorded some encouraging results, the level of that evidence is low.
- **Competitive technology risks.** Oncology is a crowded field, technologically speaking. Novel technologies including “immuno-oncology” agents will ultimately be tested in the pancreatic setting. Our view is that a loco-regional approach like OncoSil™ would remain highly relevant, given its low cost and intrinsic safety attributes.
- **Valuation risk.** Our DCF valuation implies successful development and commercialisation outcomes, all of which are uncertain. Although we are confident that our forecasts are based on realistic estimates of market size and future competitive dynamics, the adoption of new medical devices is difficult to forecast. The choice of discount rate and success probability estimates attempt to control for these risks and uncertainties, but may prove inadequate.



OncoPac-1 trial update

The OncoPac-1 trial has enrolled its first subject. OncoPac-1 is a global, multi-centre, randomised, open label clinical trial. The trial addresses the following question: does the combination of OncoSil™ and standard of care chemotherapy give better control of primary pancreatic tumours than chemotherapy alone? If it does, then OncoSil™ is a potentially practice-changing new therapy in this setting.

The start of this trial is also a signal that Oncosil Medical's management team has put the OncoSil™ asset into a position where it can be successful. When the first subject receives their treatment next month, it will be the first OncoSil™ procedure conducted for more than eight years. It has taken the company nearly two years to reconfigure almost every aspect of the product and its supporting infrastructure – product concept, dose design, manufacturing process, regulatory and quality assurance capabilities, pre-clinical and clinical data packages relating to product safety and efficacy.

The OncoPac-1 trial addresses a clinically important primary endpoint in local progression free survival (LPFS). Secondary endpoints will include overall survival (OS), progression free survival (PFS), pain scores, body weight, safety and tolerability. Based on the enrolment of 300 patients we estimate that OncoPac-1 trial may be powered to detect a ~2-3 month benefit in LPFS with statistical significance. This would also be a clinically meaningful result, in our view.

Two safety “run-in” components enrolled in parallel, followed by a 300-subject pivotal trial. Both the American and European regulatory authorities have requested data from 20 subjects. In the US FDA's case, these data should support the expansion of OncoPac-1 into its large pivotal phase. These data might also finally resolve the difficulties Oncosil has encountered in trying to obtain a CE Mark for OncoSil™. We would expect to see the first 20-subject cohort (enrolled anywhere) to be completed by May and the American component (US subjects only) recruited by July. The intended follow-up period for these trial pilots are eight weeks post-implantation.

Table 1: Selected inclusion and exclusion criteria for the first 20-patient pilot phase of OncoPac-1

Inclusion criteria	Exclusion criteria
Histologically or cytologically proven adenocarcinoma of the pancreas	Evidence of distant metastases as determined by the central reading committee
Stage III unresectable locally advanced pancreatic carcinoma	More than one primary lesion
Pancreatic target tumor diameter of ≥ 2.0 cm (shortest axis) to ≤ 6.0 cm (longest axis) and a minimum tumor volume of 14.0 cc as qualified by the central reading center	Evidence of radiographic invasion into stomach, duodenum or peritoneum (if not certain confirmation must be obtained prior to enrolment)
An ECOG Performance Status of 0 to 1 and Karnofsky Performance Status of 80 - 100	Any other health condition that would preclude participation in the study in the judgment of the principal investigator
To commence first-line standard nab-paclitaxel and gemcitabine chemotherapy, or gemcitabine alone, (per standard of care according to the approved prescribing schedule), within 7 to 14 days post enrolment, with OncoSil™ implantation to occur during the fourth (4th) week of the first chemotherapy cycle	History of malignancy, treated or untreated, within the past five years whether or not there is evidence of local recurrence or metastases, with the exception of basal cell carcinoma of the skin and cervical carcinoma in situ
Provide signed Informed Consent	In the opinion of the investigator, EUS directed implantation posing undue subject risk e.g. previous EUS-FNA was considered technically too difficult to perform, or imaging demonstrates multiple collateral vessels surrounding or adjacent to the target tumor
Adequate liver function: serum glutamic oxaloacetic transaminase/aspartate aminotransferase (SGOT/AST) and serum glutamic pyruvic transaminase/alanine aminotransferase (SGPT/ALT) $\leq 2 \times$ ULN and serum bilirubin $\leq 1.5 \times$ ULN unless Gilbert's syndrome has previously been confirmed for the subject	A known allergy or history of hypersensitivity to silicon, phosphorous or any of the OncoSil™ components
Life expectancy of at least 3 months at the time of screening as judged by the investigator	Any prior radiotherapy or chemotherapy for pancreatic cancer

Source: Oncosil



Procedural safety just as important as OncoSil™ safety in these 20-subject analysis groups. OncoPac-1 entails the first use of the product (ever) in the USA and the first treatments elsewhere for the best part of a decade. Accordingly, the procedural aspects of OncoSil™ delivery will be a key focus for both regulators. Data safety observations will probably include: a) the safety of radioactive OncoSil™ dose preparation and handling; b) ultrasound-guided endoscopic safety; c) the delivery and distribution of the radioactive intra-tumoral OncoSil™ payload; and d) use of supportive imaging modalities such as PET and CT scanning.

Pilot phase assessing both procedural safety and reconfirming OncoSil™ safety

Advances in endoscope design and radiographic imaging modalities bring more sophistication to OncoSil™ delivery compared with the studies conducted 8-10 years ago. Those older studies were conducted before PET scanning was widely available, meaning that tumour mapping and dose planning might now be done with more precision. The capabilities of ultrasound-guided endoscopes and “real time” tumour imaging have also improved. We understand that Oncosil’s internal dose modelling and simulation suggests that the implant could irradiate 50% or more of the total primary tumour volume in OncoPac-1 subjects, compared with the ~30% coverage achieved by previous practitioners.

OncoPac-1 should have enduring clinical relevance if it is successful. Pancreatic cancer is the most lethal of common malignancies and advances in treatment are hard-won. The current treatment guidelines recommend FOLFIRINOX or gemcitabine with nab-paclitaxel for LAPC patients with good performance status and gemcitabine alone for those with poor performance status. Outside Oncosil’s efforts, the ongoing mid-late stage development in pancreatic cancer looks unexciting in terms of new chemotherapeutic agents that might come into play and improve survival benchmarks.

The pancreatic cancer standard of care “benchmark” is unlikely to change – so the comparative value of OncoPac-1 should last for years

The chemotherapeutic standard of care in pancreatic cancer does differ by country. Oncosil has accommodated for these differences by allowing non-US centres more latitude on the choice of chemotherapeutic comparator. In the USA, the standard of care is unequivocally gemcitabine plus nab-paclitaxel. Elsewhere, the FOLFIRINOX¹ regime is popular on the basis of lower cost and superiority to gemcitabine alone.

OncoPac-1 enrolling the right patient group in LAPC. Excluding subjects with confirmed metastases from the trial may reduce patient heterogeneity and simplify the trial analysis. Around 30% of LAPC patients have occult micrometastases at diagnosis but induction chemotherapy can identify the patients without metastatic disease who will benefit from locoregional control². If ultimately approved for LAPC we would still expect to see usage develop within other disease stages – such as those with metastatic pancreatic cancer and those with borderline resectable pancreatic cancer.

OncoPac-1 only considers LPAC patients but the commercial opportunity extends beyond that

There’s a gap for OncoSil™ to fill because the use of chemoradiation in LAPC remains highly controversial. Key trials involving chemoradiotherapy (the combination of radiotherapy and chemotherapy) have produced mixed results with regards to survival advantage versus standard therapies in LAPC. Chemoradiation confers a survival advantage over best supportive care alone or radiotherapy alone; however, it is far more toxic. In US clinical practice, upfront chemoradiotherapy in LAPC continues to lose acceptability following last year’s LAP07 study which suggested no benefit in overall survival with chemoradiotherapy compared with chemotherapy alone. The radiation component in that study was 54 Gy delivered in 30 daily fractions over six weeks. OncoSil™ plans to deliver 100 Gy in one procedure that irradiates internally over a 12-week period.

Conventional radiotherapy has not established itself convincingly in pancreatic cancer leaving an important gap that brachytherapy might address with limited competition

¹ FOLFIRINOX is a combination of five chemotherapy drugs and is used in the UK for patients with metastatic (spread to other parts of the body) pancreatic cancer, locally advanced (inoperable but not spread elsewhere) pancreatic cancer and occasionally used as a neo-adjuvant (before surgery) agent to try to shrink a tumour for surgical removal to be possible. FOLFIRINOX started as a clinical trial which showed that a combination of the chemotherapy drugs (fluorouracil [5-FU], leucovorin, irinotecan and oxaliplatin) was better than using gemcitabine in patients with metastatic pancreatic cancer.

² Tempero M. A. *et al.* (2014). Pancreatic adenocarcinoma, Version 2.2014: Featured updates to the NCCN guidelines. *J Natl Compr Canc Netw* 12: 1083-1093.



Valuation

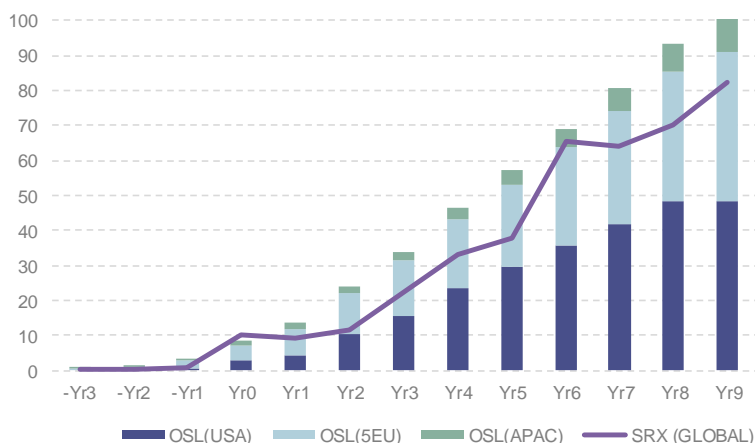
Risk-adjusted DCF valuation, revised price target of 38cps

Forecasting basis. Our valuation for Oncosil is based on a discounted cash flow (DCF) methodology as this is best able to capture the expected growth, capital intensity, risks and future optionality. We have developed an explicit forecast for OncoSil™ sales across three segments of the global cancer market: the USA, five EU (UK, France, Germany, Italy and Spain) and APAC. While we have built the model from first principles (bottom-up, patient-based model) we have also cross-checked those assumptions and forecasts with historical sales of Sirtex Medical's SIR-Spheres – in our view, the closest and most relevant comparator³. SIR-Spheres won its first major market approvals in 2002 and in FY17 we forecast it will have net sales c.\$240m. In Figure 1 below we show that our initial sales forecasts for OncoSil™ map just ahead of what SIR-Spheres achieved over the years prior to and post FDA approval.

OncoSil™ forecasts and valuation pitched at a similar level to Sirtex's SIR-Spheres product launch

OncoSil™'s trajectory may benefit from earlier approval in Europe. OncoSil™ is also targeting a "first-line" approval, which means its eligible patient population could be substantially larger at launch, compared to that which SIR-Spheres could access. SIR-Spheres was approved as a "salvage therapy" provided to patients who had failed as many as 3-4 prior lines of chemotherapy.

Figure 1: Our forecasts for OncoSil™ mapped against Sirtex's SIR-Spheres revenue; we have aligned each product's sales profile to treat the year of US FDA approval as "Yr 0"



OncoSil™ may benefit from earlier EU approval and larger initial patient population (compared with SIR-Spheres)

Source: Wilsons

Valuation upside via de-risking the technology and lowering the discount rate as firm profitability approaches.

We have assumed that Oncosil remains debt-free but dilute the valuation for future capital requirements. We have recognised a near-term weighted average cost of capital (WACC) of ~14% which anticipates the company being granted CE Marking next FY. Our terminal value is based on perpetuity growth rate of 3.5%, which reflects long-term growth in natural incidence and diagnosis rates for pancreatic and primary liver cancers in the developed world markets. The valuation is also adjusted for the risk of clinical failure by applying a "probability of success" of ~60%. If we "de-risked" the model (setting the PoS to 100%) and valued the company using a WACC of 8.5% (more in line with established medical device companies) – our valuation would be **\$2.00 per share** on a fully diluted basis.

Un-risked value in pancreatic cancer ~\$2.00 per share over a 3-year view

³ SIR-Spheres is a product based on resin microspheres that carry the radioactive element Yttrium-90. The product is used in the treatment of unresectable liver tumours such as hepatocellular carcinoma (HCC) or those associated with metastatic colorectal cancer (mCRC).

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 this year and be the subject of a large clinical trial in the US commencing in 2016. We estimate a US\$350m sales opportunity in the major pancreatic cancer markets.

Investment thesis

Oncosil Medical is an Australian medical device company developing an implantable, radioactive treatment for addressing inoperable pancreatic and liver cancers. The OncoSil™ product concept is to safely administer a radiation dose large enough to destroy a significant part of the primary tumour mass in a single procedure, with limited toxicity. This treatment outcome is not possible with conventional radiotherapy techniques. We think OncoSil™ can change clinical practice because it offers a potential solution to the number one problem reported by medical oncologists who make the pancreas their focus: the ability to “de-escalate” aggressive primary tumours that are treated with chemotherapy agents.

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)

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 their Dec-16 HY report, Oncosil had ~\$10.7m in cash and no debt

Board

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

Management

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

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Disclaimers and disclosures

Recommendation structure and other definitions

Definitions at wilsonsadvisory.com.au/Disclosures.

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