Date
16 April 2018

Theme
Company Update

Company
Oncosil Medical (OSL)

WILSONS

BUY: Cash and clinical data behind them now

We are re-initiating coverage of Oncosil Medical with a BUY rating, following a Research blackout period. Our new 12-month price target is $0.43 per share. The OncoSil™ medical device has demonstrated interesting safety and efficacy signals in single-arm, pilot clinical trials. Oncosil also raised sufficient capital to pursue European approval, initiate commercial sales and to launch a pivotal trial aimed at US product registration. Their investigational medical device offers advantages over standard radiotherapy approaches – delivering a decisive dose of radiation to pancreatic tumours in a single procedure with good safety. If efficacy is borne out in randomised trials, the product could be highly relevant to how treatment of locally advanced pancreatic cancer evolves.

Key points

Positive interim safety and tumour response data in unresectable pancreatic cancer (LAPC). The pooled results from Oncosil's PanCO trial suggest that its brachytherapy product OncoSil™ is safe and that it may possess useful tumour-shrinking activity. Three of the first 20 patients have undergone potentially curative resections, with another three under consideration. OncoSil™ used in combination with the chemotherapeutic standard of care has achieved impressive tumour shrinkage, setting the product up for a potential approval in Europe and a global pivotal clinical trial.

Fully funded to attain CE Mark and commence pivotal phase of OncoPac-1 trial. Oncosil has raised approximately $14.7m in new equity to complete the preliminary phases of its PanCO and OncoPac-1 trials, support European commercialisation and commence a global, registration-directed randomised controlled trial under an Investigational Device Exemption from US FDA.

Remodelling initial sales expectations. We review our model assumptions for global OncoSil™ sales in light of revised development timelines and new clinical information. We assess a US$1B+ per annum opportunity for the product and model >$100m in US sales, five years post launch.

Valuation. Our price target is lifted to $0.43 per share now that OncoSil™ has demonstrated encouraging, early clinical performance. Our previous valuation anticipated future capital raising events, the terms of which were broadly consistent with the recent 12¢ placement and SPP. Further de-risking events (CE Mark, pivotal trial success, FDA approval, corporate activity) can support valuations up to $2.00 per share over the next five years.

Risks and catalysts

Catalysts: a) further data from the OncoPac-1 and PanCO trials; b) CE Mark and product launches; c) IDE approval for OncoPac-1; d) potential corporate activity. **Risks**: a) clinical trial and regulatory setbacks; b) competitor programs in pancreatic cancer; c) product safety signals.

Recommendation	**BUY**
12-mth target price (AUD)	**$0.43**
Share price @ 12-Apr-18 (AUD)	$0.14
Forecast 12-mth capital return	219.6%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	**219.6%**
Market cap	$76m
Enterprise value	$63m
Shares on issue	565m
Sold short	
ASX 300 weight	n/a
Median turnover/day	$0.1m

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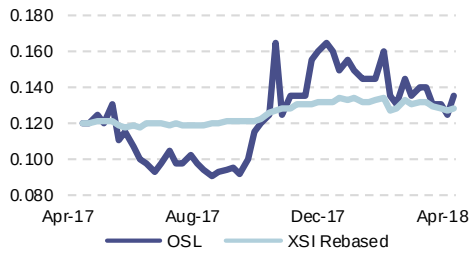
12-mth price performance ($)



	1-mth	6-mth	12-mth
Abs return (%)	-3.6	8.0	12.5
Rel return (%)	-0.7	6.4	5.9

Earnings forecasts

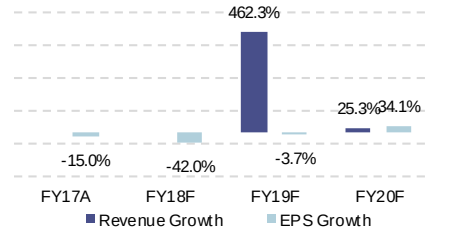
Year-end June (AUD)	FY16A	FY17A	FY18F	FY19F	FY20F
NPAT rep ($m)	-4.8	-7.0	-10.0	-11.4	-7.7
NPAT norm ($m)	-4.8	-7.0	-10.0	-11.4	-7.7
Consensus NPAT ($m)			-12.7	27.0	-7.9
EPS norm (cps)	-1.1	-1.3	-1.9	-1.9	-1.3
EPS growth (%)	-40.1	-15.0	-42.0	-3.7	34.1
P/E norm (x)	-11.9	-10.3	-7.3	-7.0	-10.6
EV/EBITDA (x)	-12.9	-8.8	-6.3	-5.5	-8.2
FCF yield (%)	-6.1	-8.1	-11.8	-15.3	7.8
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, S&P Capital IQ

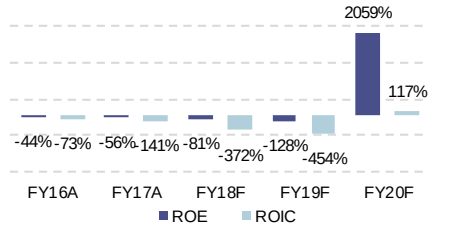
Key changes

		01-Mar	After	Var %
NPAT:	**FY18F**	-12.7	-10.0	N/A
norm	**FY19F**	-11.4	-11.4	N/A
($m)	**FY20F**	-6.2	-7.7	N/A
EPS:	**FY18F**	-2.1	-1.9	N/A
norm	**FY19F**	-1.7	-1.9	N/A
(cps)	**FY20F**	-0.9	-1.3	N/A
DPS:	**FY18F**	0.0	0.0	0.0%
(cps)	**FY19F**	0.0	0.0	0.0%
	FY20F	0.0	0.0	0.0%
Price target:		0.38	0.43	13.5%
Rating:		**BUY**	**BUY**	

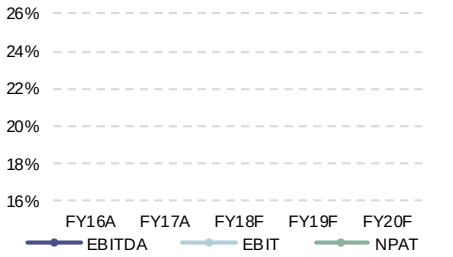
Growth rates



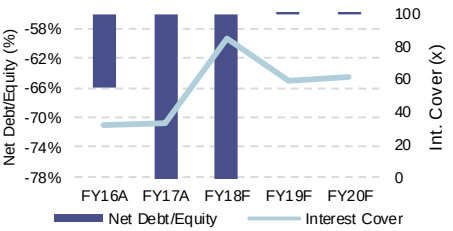
Returns



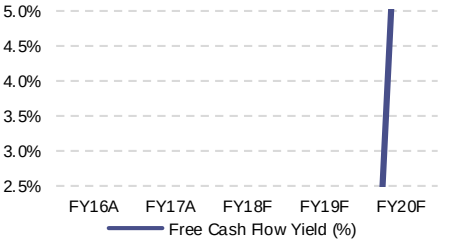
Margin trends



Solvency



Free cash flow yield



Interims ($m)

	1H17A	2H17A	1H18A	2H18E
Sales revenue	0.0	0.0	0.0	0.2
EBITDA	-3.2	-4.0	-4.6	-5.5
EBIT	-3.2	-4.0	-4.6	-5.5
Net profit	**-3.1**	**-3.9**	**-4.5**	**-5.5**
Norm EPS	**-0.6**	**-0.7**	**-0.8**	**-1.0**
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

	FY13A	FY14A	FY15A	FY16A	FY17A	FY18F	FY19F	FY20F
Revenue growth (%)	-100.0						462.3	25.3
EBIT growth (%)	-104.9	382.6	-35.9	62.5	46.9	39.6	15.1	-33.0
NPAT growth (%)	-105.1	379.7	-31.7	65.6	47.1	42.3	14.5	-33.0
EPS growth (%)	**-101.9**	**139.6**	**-40.4**	**40.1**	**15.0**	**42.0**	**3.7**	**-34.1**
EBIT/sales (%)						-5,052.7	-1,034.3	-552.9
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**	**-37.6**	**-61.2**	**-93.1**	**-126.7**	**-70.2**
ROE (%)	**-14.5**	**-34.7**	**-41.4**	**-40.2**	**-68.4**	**-135.4**	**2,651.4**	**193.8**

Financial ratios

	FY13A	FY14A	FY15A	FY16A	FY17A	FY18F	FY19F	FY20F
PE (x)	-23.8	-9.9	-16.7	-11.9	-10.3	-7.3	-7.0	-10.6
EV/EBITDA (x)	-64.6	-13.4	-20.9	-12.9	-8.8	-6.3	-5.5	-8.2
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FCF yield (%)	-0.6	-8.4	-0.3	-6.1	-8.1	-11.8	-15.3	7.8
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	0.0

Profit and loss ($m)

	FY13A	FY14A	FY15A	FY16A	FY17A	FY18F	FY19F	FY20F
Sales revenue	0.0	0.0	0.0	0.0	0.0	0.2	1.1	1.4
EBITDA	-1.0	-4.7	-3.0	-4.9	-7.2	-10.1	-11.6	-7.7
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**	**-7.2**	**-10.1**	**-11.6**	**-7.8**
Net interest expense	-0.1	-0.2	-0.2	-0.2	-0.2	-0.1	-0.2	-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**	**-7.0**	**-10.0**	**-11.4**	**-7.7**
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**	**-7.0**	**-10.0**	**-11.4**	**-7.7**

Cash flow ($m)

	FY13A	FY14A	FY15A	FY16A	FY17A	FY18F	FY19F	FY20F
EBITDA	-1.0	-4.7	-3.0	-4.9	-7.2	-10.1	-11.6	-7.7
Interest & tax	-0.1	-0.2	2.8	0.0	0.0	-0.1	-0.2	-0.1
Working cap/other	0.6	-1.4	0.1	0.3	1.1	1.2	0.3	14.0
Operating cash flow	**-0.5**	**-6.4**	**-0.2**	**-4.6**	**-6.1**	**-8.9**	**-11.5**	**6.1**
Maintenance capex	0.0	0.0	0.0	-0.1	-0.1	-0.1	-0.2	-0.2
Free cash flow	**-0.5**	**-6.4**	**-0.2**	**-4.6**	**-6.2**	**-9.0**	**-11.7**	**5.9**
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	-0.2	-4.7	0.0	-0.5	3.4	0.0	0.0	0.0
Cash flow pre-financing	**-0.7**	**-11.1**	**-0.2**	**-5.1**	**-2.7**	**-9.0**	**-11.7**	**5.9**
Funded by equity	1.8	10.3	0.0	12.4	1.0	14.0	0.0	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	1.8	-5.0	11.7	-5.9

Balance sheet summary ($m)

	FY13A	FY14A	FY15A	FY16A	FY17A	FY18F	FY19F	FY20F
Cash	3.5	2.7	2.5	9.8	8.0	13.0	1.3	7.2
Current receivables	0.0	0.1	0.1	2.6	3.5	2.5	2.6	3.2
Current inventories	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net PPE	0.0	0.0	0.1	0.1	0.1	0.2	0.3	0.5
Intangibles/capitalised	2.6	2.6	0.0	0.0	0.0	0.0	0.0	0.0
Total assets	**6.2**	**12.3**	**7.4**	**15.9**	**11.8**	**15.8**	**4.4**	**11.1**
Current payables	0.1	0.0	0.2	1.0	1.5	1.0	1.0	0.4
Total debt	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total liabilities	**0.2**	**0.1**	**0.4**	**1.1**	**1.7**	**1.2**	**1.2**	**15.1**
Shareholder equity	**6.1**	**12.2**	**7.0**	**14.8**	**10.1**	**14.6**	**3.2**	**-4.0**
Total funds employed	**6.1**	**12.2**	**7.0**	**14.8**	**10.1**	**14.6**	**3.2**	**-4.0**

Oncosil Medical – BUY: Investing to build a brachytherapy franchise

Investment thesis

We are re-initiating coverage of Oncosil Medical with a BUY rating, following a Research blackout period. Our new 12-month price target is $0.43 per share. The OncoSil™ medical device has demonstrated interesting safety and efficacy signals in single-arm, pilot clinical trials. Oncosil also raised sufficient capital to pursue European approval, initiate commercial sales and to launch a pivotal trial aimed at US product registration. Their investigational medical device offers advantages over standard radiotherapy approaches – delivering a decisive dose of radiation to pancreatic tumours in a single procedure with good safety. If efficacy is borne out in randomised trials, the product could be highly relevant to how treatment of locally advanced pancreatic cancer evolves.

Outlook

Earlier this month Oncosil Medical reported detailed results from its PanCO clinical trial, suggesting that its candidate medical device product OncoSil™ is safe, can be deployed via endoscope without complications and may significantly enhance tumour shrinkage when combined with chemotherapy. The company also conducted a successful capital raising and announced more detail about the next steps for OncoSil™ development and commercialisation. The catalysts to think about over the next few years include:

a) PanCO data forming the basis for European approval (CE Mark);

b) First commercial sales as early adopters interested in the ability to “downstage” primary pancreatic tumours so that they can be surgically removed (resection);

c) FDA granting approval for Oncosil to conduct a large, randomised controlled clinical trial involving US subjects (which would potentially provide the evidentiary basis for approval); and

d) potential partnering for commercialisation in selected countries.

Valuation

We use a discounted cash flow (DCF) valuation model to analyse the potential for OncoSil™ and Oncosil’s valuation over the next five years. Oncosil’s recent clinical success lifts our 12-month forward, risked valuation to $0.43 per share, fully diluted for new equity capital issued at $0.12 per share and outstanding options. We model future valuation upside using four stages of OncoSil™ development and commercialisation:

- CE Mark enabling certain ex-USA marketing authorisations;
- Market access, by which we mean appropriate reimbursement outcomes and demand measured by sales;
- Execution of a large (n > 300) global RCT to demonstrate a statistically significant, clinically meaningful benefit from adding OncoSil™ to the chemotherapeutic standard of care; and
- Corporate activity – we view Oncosil Medical as a potential candidate for high value commercial partnering and/or acquisition.

Our five-year, unrisked valuation is upgraded to $2.00 per share. The increase reflects stronger-than-expected clinical signals from PanCO data, particularly with respect to supporting higher-than-expected tumour shrinkage and resection rates.

OncoSil™ clinical development update

The preliminary PANCO results, reviewed

We take three observations away from the new clinical data Oncosil recently released to the market:

- Product maintained its clean safety profile;
- A potential additive benefit over the standard of care, when used in combination with chemotherapy, in unresectable LAPC patients;
- Clear potential to "down-stage" primary pancreatic tumours to become eligible for surgery with curative intent.

Clinical trial design points, recapped

Oncosil's trial program consists of two trials. Both studies seek to evaluate the safety of OncoSil™, when the device is administered to unresectable LAPC patients in combination with chemotherapy.

a) PanCO is recruiting 45 patients from Australia, the UK and Belgium. Physicians have a choice of chemotherapy "background" in this trial: i) FOLFIRINOX (widely prescribed in Europe); or ii) a combination of *nab*-paclitaxel and gemcitabine (a newer treatment option still establishing itself in Europe due to reimbursement considerations). PanCO should form the basis for CE Mark and other product approvals outside USA. PanCO has enrolled 40 patients, of which 31 have received treatment.

b) OncoPac-1 aims to recruit 20 patients, 10 of which must be treated at trial sites in the USA. Physicians must use the *nab*-paclitaxel/gemcitabine regimen. OncoPac-1 is a "safety run-in" or pilot trial. US FDA will use its results in deciding to allow Oncosil to commence a larger, randomised controlled trial ultimately required for US product approval. OncoPac-1 has enrolled and implanted just one patient as at the time of writing.

The primary objective is to show safety and tolerability of both OncoSil™ and its delivery procedure (ultrasound guided endoscopy) in combination with chemotherapy. Other assessments include local progression free survival (in the pancreas and at other sites, assessed separately), tumour responses, overall survival and pain relief. As both PanCO and OncoPac-1 are single-arm studies (and therefore uncontrolled), these pilot trials were not designed to detect OncoSil™'s specific, incremental anti-cancer activity.

Recently, Oncosil reported data from the first 20 patients enrolled in PanCO.

OncoSil™ was safe and well tolerated. Device safety looks favourable and is a key point of differentiation from other modes of radiotherapy. OncoSil™'s product specification of 100 Grays of radiation, delivered in a single procedure, with minimal additive toxicity seems superior to today's external beam radiotherapy (EBR) approaches. EBR delivery is often complicated by its attendant toxicity which limits how much dose can be delivered in a given sitting. EBR courses can run over 5-6 weeks involving 20-30 daily visits.

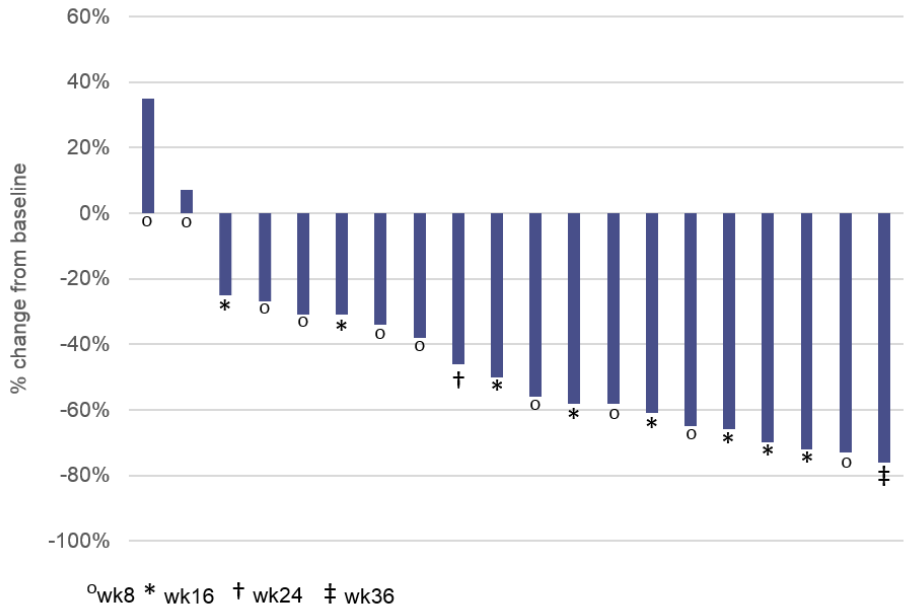
There were no serious adverse events attributed to the OncoSil™ device or its deployment. Importantly, there was no evidence of radiation toxicity. It is encouraging to see a uniformity in device performance across different healthcare institutions and treating physicians.

Response rate of 25% is at least consistent with published results from chemotherapy. The standard for assessing tumour responses is the Response Criteria In Solid Tumours (RECIST) which measures changes in a target tumour's longest dimension. There have been no complete responses in PanCO as yet (unsurprising) but 25% of patients have had partial responses (a ≥30% reduction in the tumour's longest diameter). For reference, *nab*-placlitaxel+gemcitabine chemotherapy is associated with response rates of ~23%[1] and FOLFIRONOX typically achieves ~27%[2].

Disease control rate (DCR) of 87% at week 16. In oncology, the DCR is a term used to describe the proportion of patients who achieve a complete response, partial response or at least experience a stabilisation of their disease. For reference, standard of care chemotherapy mainstays *nab*-paclitaxel+gemcitabine and FOLFIRINOX achieve DCRs of approximately 78%[3] and 84%[4], respectively in LAPC cases. DCR is not a formal endpoint of the PanCO or OncoPac-1 studies but it is a widely reported statistic in the pancreatic cancer literature.

Consistent and impressive volumetric reductions in target tumours. Tumour shrinkage is an important clinical objective because primary pancreatic malignancies drive the distressing symptoms of pancreatic cancer including pain, pancreatic insufficiency and biliary obstruction. Eighteen of 20 patients (90%) achieved ≥20% reductions in tumour volume. Encouragingly, some of those reductions appear durable out to 16, 24 or even 36 weeks post-implantation (bearing in mind that the OncoSil™ device only emits radiation for ~12 weeks *in situ*).

Figure 1: Best tumour volumetric changes achieved in the first 20 PanCO patients



Source: Oncosil, Wilsons

[1] Kunzmann, V. et al. (2017) Tumour reduction in primary and metastatic pancreatic cancer lesions with nab-placlitaxel and gemcitabine Pancreas 46: 203 – 208.

[2] Faris, J. E. et al. (2013) FOLFIRINOX in locally advanced pancreatic cancer: The Massachusetts General Hospital Cancer Centre experience Oncologist 18: 543 – 548.

[3] See Celgene press release: http://ir.celgene.com/releasedetail.cfm?releaseid=1054802

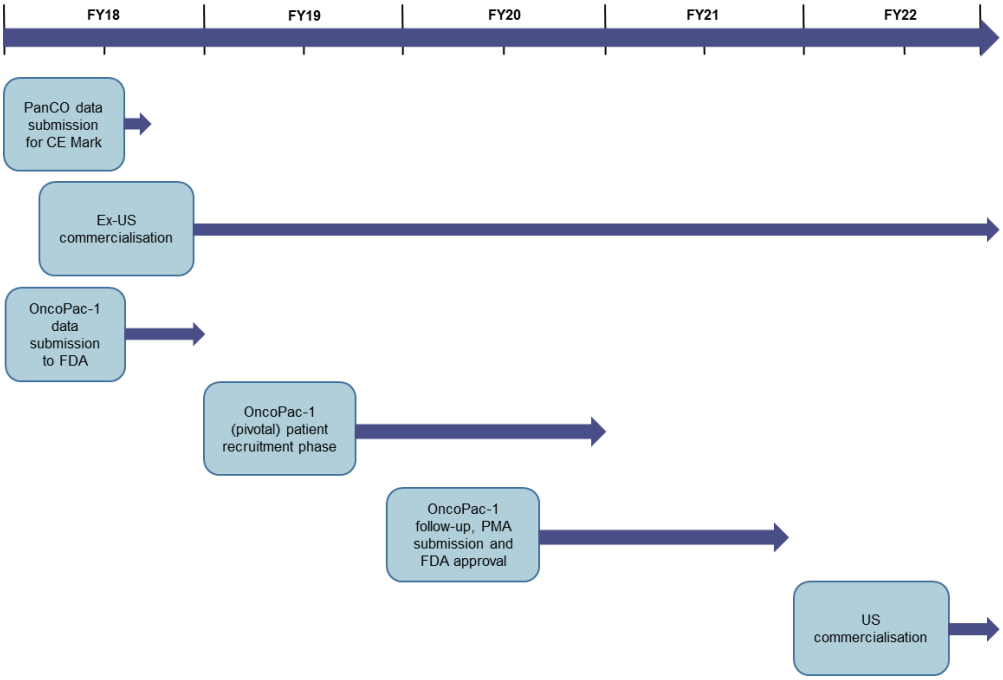
[4] Lakatos, G. et al. (2017) Efficacy and safety of FOLFIRINOX in locally advanced pancreatic cancer. Pathol. Oncol. Res. 23: 753 – 759.

Resection rates unexpectedly high and a driver of early adopters if consistently achieved. Three of the first 20 PanCO patients have subsequently undergone resection or the surgical excision of their primary tumour with clear margins. A further three patients are now being considered for surgery. The device has achieved some good volumetric reductions and this may have played into what appears to be a favourable resection rate. Resection feasibility is as much a function of the tumour's position relative to important structures and the surgical risk entailed. Nonetheless, if resection rate turns out to be 20% or higher, then this may be interesting enough to encourage early adoption once OncoSil™ becomes commercially available. If the device is priced appropriately, good resection outcomes could even drive private pay demand.

Further studies planned

Oncosil's pivotal trial plans. Subject to FDA approval, Oncosil will advance OncoSil™ into a randomised, controlled trial. The primary endpoint is local progression free survival (LPFS). Secondary endpoints include progression free survival (PFS), overall survival (OS), pain scores, body weight, safety and tolerability. Quality of life measures will be also be studied. Interestingly, Oncosil chose to restrict its study to patients with locally advanced disease without metastases. Minimising the level of potential interference (and mortality) associated with distant metastatic tumours (liver, lung, bone) may make the trial results easier to interpret. All patients will be followed up until they experience disease progression. The primary endpoint is assessable at 16 weeks post-implantation but all patients will be followed for overall survival until death, or until the last enrolled patient has completed 52 weeks of overall survival follow-up.

Figure 2: Oncosil's development program LAPC



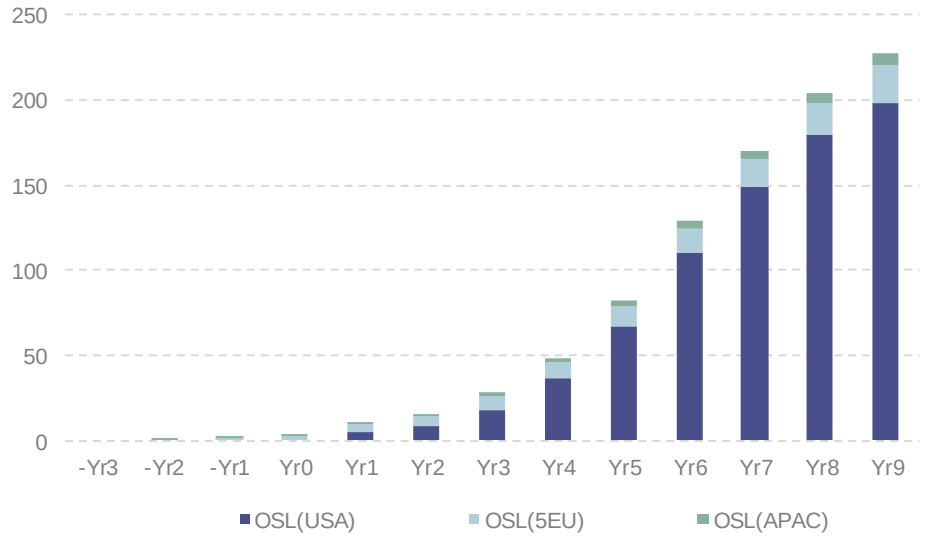
Source: Wilsons estimates

Market model

Assumptions about OncoSil™ commercialisation

- Eligible patient population. The device is best suited to the 95% of pancreatic cancer cases characterised as adenocarcinomas. Approximately 85% of these cases present as unresectable disease.
- Target patient characteristics. We model the population of newly diagnosed patients being split 50:50 as to those with locally advanced pancreatic cancer (LAPC) and those who have already developed metastatic disease. We assume that 67% of LAPC patients and 40% of metastatic patients seek treatment.
- Pricing. We are assuming a flat, net average selling price to Oncosil of US$18,000 per course in USA, €10,000 per course in major European countries and A$10,000 per dose in the rest of the world including Australia and Asia.
- US market penetration. We are modelling a linear pathway of product adoption reaching approximately 25% of the eligible population by 10 years post launch.
- ROW market penetration. We have only made very modest allowance for European and rest-of-world sales. These may be added to in the event that Oncosil pursues partnering arrangements in these jurisdictions.

Figure 3: Initial sales projections for OncoSil™ by jurisdiction, in years post-launch



Source: Oncosil, Wilsons

Market model

OncoSil - Pancreatic Cancer Market Model	FY18	FY19	FY20	FY21	FY22	FY23	FY24	FY25	FY26	FY27	FY28	FY29	FY30
USA													
Incident population	42,885	43,314	43,747	44,184	44,626	45,073	45,523	45,979	46,438	46,903	47,372	47,845	48,324
Eligible popn (unresectable adenocarcinomas)	34,630	34,976	35,326	35,679	36,036	36,396	36,760	37,128	37,499	37,874	38,253	38,635	39,022
Locally advanced pancreatic cancer (LAPC)	16,276	16,439	16,603	16,769	16,937	17,106	17,277	17,450	17,624	17,801	17,979	18,159	18,340
Metastatic pancreatic cancer (MPC)	18,354	18,537	18,723	18,910	19,099	19,290	19,483	19,678	19,874	20,073	20,274	20,477	20,681
Pts seeking treatment (67% LAPCs + 40% MPCs)	**18,246**	**18,429**	**18,613**	**18,799**	**18,987**	**19,177**	**19,369**	**19,563**	**19,758**	**19,956**	**20,155**	**20,357**	**20,560**
ASP (US$ per dose)	18,000	18,000	18,000	18,000	18,000	18,000	18,000	18,000	18,000	18,000	18,000	18,000	18,000
Units	-	-	-	250	375	750	1,500	2,775	4,163	4,995	5,894	6,778	6,778
' dose grow th					50%	100%	100%	85%	50%	20%	18%	15%	0%
Implied penetration in eligible popn				*0.7%*	*1.0%*	*2.1%*	*4.1%*	*7.5%*	*11.1%*	*13.2%*	*15.4%*	*17.5%*	*17.4%*
Net sales (US$m)	**-**	**-**	**-**	**4.5**	**6.8**	**13.5**	**27.0**	**50.0**	**74.9**	**89.9**	**106.1**	**122.0**	**122.0**
Net sales (A$m)	**-**	**-**	**-**	**5.6**	**8.4**	**16.9**	**33.8**	**62.4**	**93.7**	**112.4**	**132.6**	**152.5**	**152.5**
5EU													
Incident population	88,058	88,939	89,828	90,726	91,634	92,550	93,475	94,410	95,354	96,308	97,271	98,244	99,226
Eligible popn (unresectable adenocarcinomas)	71,107	71,818	72,536	73,261	73,994	74,734	75,481	76,236	76,999	77,768	78,546	79,332	80,125
Locally advanced pancreatic cancer (LAPC)	33,420	33,754	34,092	34,433	34,777	35,125	35,476	35,831	36,189	36,551	36,917	37,286	37,659
Metastatic pancreatic cancer (MPC)	37,687	38,063	38,444	38,829	39,217	39,609	40,005	40,405	40,809	41,217	41,629	42,046	42,466
Pts seeking treatment (67% LAPCs + 40% MPCs)	**37,466**	**37,841**	**38,219**	**38,601**	**38,987**	**39,377**	**39,771**	**40,169**	**40,571**	**40,976**	**41,386**	**41,800**	**42,218**
ASP (EUR per dose)	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000
Units	-	30	75	150	270	405	547	683	820	984	1,132	1,302	1,497
' dose grow th			150%	100%	80%	50%	35%	25%	20%	20%	15%	15%	15%
Implied penetration in eligible popn	*0.0%*	*0.0%*	*0.1%*	*0.2%*	*0.4%*	*0.5%*	*0.7%*	*0.9%*	*1.1%*	*1.3%*	*1.4%*	*1.6%*	*1.9%*
Net sales (EURm)	**-**	**0.3**	**0.8**	**1.5**	**2.7**	**4.1**	**5.5**	**6.8**	**8.2**	**9.8**	**11.3**	**13.0**	**15.0**
Net sales (A$m)	**-**	**0.4**	**1.1**	**2.1**	**3.9**	**5.8**	**7.8**	**9.8**	**11.7**	**14.1**	**16.2**	**18.6**	**21.4**
ROW													
Incident population	100,000	101,000	102,010	103,030	104,060	105,101	106,152	107,214	108,286	109,369	110,462	111,567	112,683
Eligible popn (unresectable adenocarcinomas)	80,750	81,558	82,373	83,197	84,029	84,869	85,718	86,575	87,441	88,315	89,198	90,090	90,991
Locally advanced pancreatic cancer (LAPC)	37,953	38,332	38,715	39,102	39,494	39,888	40,287	40,690	41,097	41,508	41,923	42,342	42,766
Metastatic pancreatic cancer (MPC)	42,798	43,225	43,658	44,094	44,535	44,981	45,430	45,885	46,344	46,807	47,275	47,748	48,225
Pts seeking treatment (67% LAPCs + 40% MPCs)	**42,547**	**42,973**	**43,402**	**43,836**	**44,275**	**44,718**	**45,165**	**45,616**	**46,072**	**46,533**	**46,999**	**47,469**	**47,943**
ASP (A$ per dose)	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000
Units	-	26	52	104	130	163	203	254	317	397	496	620	775
' dose grow th			100%	100%	25%	25%	25%	25%	25%	25%	25%	25%	25%
Implied penetration in eligible popn	*0.0%*	*0.0%*	*0.1%*	*0.1%*	*0.2%*	*0.2%*	*0.2%*	*0.3%*	*0.4%*	*0.4%*	*0.6%*	*0.7%*	*0.9%*
Net sales (A$m)	**-**	**0.3**	**0.5**	**1.0**	**1.3**	**1.6**	**2.0**	**2.5**	**3.2**	**4.0**	**5.0**	**6.2**	**7.7**
Global Dose Sales	-	56	127	504	775	1,318	2,250	3,712	5,300	6,376	7,522	8,700	9,050
Global gross revenue ($Am)	**-**	**0.7**	**1.6**	**8.8**	**13.6**	**24.3**	**43.6**	**74.7**	**108.5**	**130.4**	**153.7**	**177.3**	**181.6**

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™ 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 are re-initiating coverage of Oncosil Medical with a BUY rating, following a Research blackout period. Our new 12-month price target is $0.43 per share. The OncoSil™ medical device has demonstrated some interesting safety and efficacy signals in single-arm, pilot clinical trials. Oncosil has also raised sufficient capital to pursue European approval, initiate commercial sales and to launch a pivotal trial aimed at US product registration. Their investigational medical device offers advantages over standard radiotherapy approaches – delivering a decisive dose of radiation to pancreatic tumours in a single procedure with good safety. If efficacy is borne out in randomised trials, the product could be highly relevant to how treatment of locally advanced pancreatic cancer evolves.

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

- As at end 1H18, Oncosil had ~$5.2m in cash and no debt.
- Oncosil subsequently raised approximately $14.7m capital.

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

- Chris Roberts (Chairman)
- Daniel Kenny (Managing Director)
- Roger Aston (Non-Executive Director)
- Martin Cross (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)
- Tom Milicevic (CFO)
- Ash Soman (CMO)
- Charles Rowland (President – US Operations)

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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Disclaimers and disclosures

Recommendation structure and other definitions

Definitions at wilsonsadvisory.com.au/Disclosures.

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