Date
09 August 2017

Theme
Company Update

Company
Oncosil Medical (OSL)

WILSONS

BUY: OncoPac-1 trial progress and validation

We maintain our BUY rating on Oncosil Medical with a 12-month price target of $0.38 per share. The company's OncoPac-1 clinic trial in pancreatic cancer made progress, recruiting 14 of the 20 patients it needs to prosecute its case for European marketing authorisation. In the USA, the FDA will now accept up to 10 of these patients in its own 20-patient evaluation, before expanding the trial into its pivotal phase (randomising ~300 patients). The opportunity for local disease control remains very pressing in the treatment of locally advanced pancreatic cancer. In this report we summarise recent feedback from our consultants and literature surveys that describe a clear market position for the OncoSil™ product as a treatment that offers the potential for rapid de-escalation of the primary tumour with good safety and low toxicity.

Recommendation	**BUY**
12-mth target price (AUD)	**$0.38**
Share price @ 04-Aug-17 (AUD)	$0.10
Forecast 12-mth capital return	283.4%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	**283.4%**
Market cap	$48m
Enterprise value	$40m
Shares on issue	487m
Sold short	
ASX 300 weight	n/a
Median turnover/day	$0.0m

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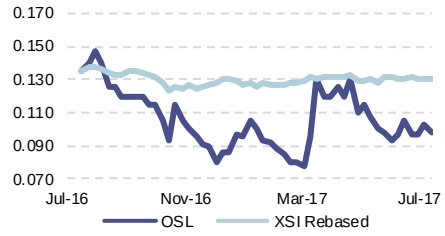
12-mth price performance ($)



	1-mth	6-mth	12-mth
Abs return (%)	-6.7	-2.0	-27.4
Rel return (%)	-6.1	-6.1	-23.8

Key points

OncoPac-1 trial recruitment update. The pilot phase of Oncosil Medical's clinical trial has recruited 14 of the 20 patients it needs to reanimate the campaign seeking marketing authorisation in Europe (CE Mark). As a reminder, the OncoPac-1 trial is designed to test the company's OncoSil™ medical device in the treatment of locally advanced pancreatic cancer (LAPC). European regulatory bodies will consider the results from the first 20 patients as part of their ongoing evaluation. With 8 centres open now in AU/UK we are looking for the requisite 20 procedures to be completed and analysed by the end of the year, enabling European and other approvals through 2018. The FDA is now willing to accept data from up to 10 of these non-US patients in its own 20-patient data "run in" safety assessment. The FDA will then decide whether to grant Oncosil the full Investigational Device Exemption (IDE) status it needs to move into the pivotal phase of OncoPac-1, which will support a Pre-market approval (PMA) application for US marketing.

Cash runway to demonstrating clinical and commercial feasibility. Oncosil reported $8.0m cash at the end of FY17 which is adequate to complete these two parallel pilot projects. The preliminary data will not reveal OncoSil™ specific efficacy (administered alongside chemotherapy) but will validate the safety and reproducibility of the delivery procedures across multiple centres.

The opportunity for loco-regional radiotherapy in LAPC is undiminished, notwithstanding the failure of SIR-Spheres in treating liver metastases. We've had a number of incoming calls and conversations with investors asking whether Sirtex's disappointing results earlier this year with its liver-directed cancer therapy (SIR-Spheres) in any way precludes OncoSil™ from being successful as a pancreas-directed therapy. In this report we review the feedback we've received from both consultants and the recent literature. The key points that differentiate OncoSil™ are: a) the choice of primary endpoint (local progression free survival in the pancreas); b) the strong focus on local disease control and its role in tumour downstaging for resection and managing symptom burden (especially pain); and c) the technological limitations associated with conventional chemotherapies and radiotherapy modalities.

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 over its first decade post major approvals.

Risks and catalysts

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. OncoSil is a high risk investment. **Catalysts**: a) obtaining CE Mark; b) IDE trial progress; c) EU marketing approval and first sales; d) Board renewal.

Key changes

		03-Apr	After	Var %
NPAT:	**FY17F**	-8.8	-8.8	0.0%
norm	**FY18F**	-12.7	-12.7	N/A
($m)	**FY19F**	-11.5	-11.5	N/A
EPS:	**FY17F**	-1.7	-1.9	N/A
norm	**FY18F**	-2.2	-2.1	N/A
(cps)	**FY19F**	-1.9	-1.7	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:		0.38	0.38	-1.3%
Rating:		**BUY**	**BUY**	

Price target	Valuation	Price target
DCF methodology		
WACC estimate (%)	14.5	
Terminal growth rate (%)	3.5	
PV of forecast FCFs ($m)	13.8	
PV of terminal value ($m)	237.5	
Enterprise value ($m)	251.3	
Net debt (cash) ($m)	-8.0	
Equity value ($m)	259.3	

Price target ($ /share) **0.38**

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	44.2	-9.3	-46.6
EPS growth (%)	**-101.9**	**139.6**	**-40.4**	**51.5**	**50.8**	**15.0**	**-20.1**	**-47.8**
EBIT/sales (%)					-960.9	-4,284.9	-802.7	-182.9
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**	**-44.5**	**-108.9**	**-144.1**	**-91.3**	**-40.8**
ROE (%)	**-14.5**	**-34.7**	**-41.4**	**-48.5**	**-131.0**	**-230.6**	**-370.5**	**-1,533.9**

Interims ($m)				
Half-year (AUD)	**Dec 15**	**Jun 16**	**Dec 16**	**Jun 17**
	1HA	**2HA**	**1HA**	**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**	**-1.2**
EBIT/sales (%)			-344.6	
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	-8.0	-3.5
Net debt/equity (%)	<0	<0	<0
Net debt/EV (%)	**<0**	**<0**	**<0**
Current ratio (x)	14.6	4.9	4.1
Interest cover (x)	31.2	39.9	68.1
Adj cash int cover (x)	**30.3**	**20.5**	**74.6**
Debt/cash flow (x)	0.0	0.0	0.0
Net debt (cash)/share ($)	<0	<0	<0
NTA/share ($)	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)	388	388	474	474
Diluted EPS (c)	**-1.2**	**-1.2**	**-1.9**	**-1.9**

Returns				
	FY16A	**FY17F**	**FY18F**	**FY19F**
ROE (%)	-44	-82	-250	-243
ROIC (%)	-73	-339	>999	<-999
Incremental ROE	-143	>999	68	-356
Incremental ROIC	60	99	105	112

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	-0.2
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**	**-6.1**
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**	**-6.1**

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	-0.2
Working cap/other	0.6	-1.4	0.1	0.3	4.8	-0.7	0.1	14.6
Operating cash flow	**-0.5**	**-6.4**	**-0.2**	**-4.6**	**-4.3**	**-13.7**	**-11.6**	**8.1**
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**	**-4.4**	**-13.9**	**-11.8**	**7.9**
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
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**	**-1.8**	**-13.9**	**-11.8**	**7.9**
Funded by equity	1.8	10.3	0.0	12.4	0.0	9.4	14.1	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	4.5	-2.3	-7.9

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	8.0	3.5	5.8	13.7
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	0.0	0.0	0.0	0.0
Total assets	**6.2**	**12.3**	**7.4**	**15.9**	**8.4**	**4.5**	**7.1**	**15.6**
Current payables	0.1	0.0	0.2	1.0	1.6	1.0	1.0	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**	**1.7**	**1.1**	**1.1**	**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**	**3.4**	**6.0**	**0.4**
Total funds employed	**6.1**	**12.2**	**7.0**	**14.8**	**6.7**	**3.4**	**6.0**	**0.4**

Oncosil Medical – Clinical trial progress and further insights on the OncoSil™ investment case

Progress report on OncoSil™ clinical development and regulatory

OncoPac-1 recruitment update. Oncosil Medical's major clinical trial went quiet after enrolling its first patient in late March, so last week's progress update was welcome. OncoPac-1 is a complex clinical trial from a participating oncology centre's perspective, primarily on account of the radiation safety issues it presents and the multidisciplinary nature of its protocol (chemotherapy + brachytherapy). It has taken more time than anticipated to support centres through their own Institutional Review Board (IRB) reviews, operator training and site initiations. Since April, trial recruitment has improved significantly, enrolling a further 13 subjects and implanting 5. Ten sites are now open (5 in Australia, 3 in the UK and 2 in the USA). Another 5 centres are expected to open in coming weeks having closed out their respective ethics approvals.

We understand that the first procedures were performed without complication and with pleasing results, procedurally speaking. Anecdotally, the ease/consistency of implantation and general procedural safety were similar to the early work (also in LAPC patients) published in 2008 by investigators at Guy's and St Thomas' NHS Trust in London (who are backing their work with the OncoSil™ device and participating in the OncoPac-1 trial).

CE Mark and launches next year – but not a big focus for us. Recruitment progress is important for reanimating the company's stalled campaign in seeking marketing authorisation for their product in Europe (CE Mark). European regulatory reviewers are expected to consider the results from the first 20 patients in OncoPac-1, as part of their ongoing evaluation of OncoSil™. With 8 trial centres open now in AU/UK we are looking for these 20 procedures to be completed and analysed by the end of this year, enabling European and other approvals over the course of 2018. Our sales expectations following CE Mark are very modest because we do not expect rapid adoption of the product until higher quality evidence describing its efficacy and safety becomes available from the large randomised phase of OncoPac-1 in a few years' time.

Progressing to the pivotal phase of OncoPac-1 the most valuable exercise for Oncosil. The FDA is also waiting to perform its own 20-patient evaluation of OncoPac-1 data before granting Oncosil the full Investigational Device Exemption (IDE) status it needs to expand the number of participating centres in the USA. The FDA is now willing to include data from up to 10 patients treated outside the USA in its analysis, which should speed up Oncosil's progress in that country, where two trial centres are now open (MD Anderson and Moffitt) and another three are initiating. As a reminder, the pivotal phase of OncoPac-1 is an international, multicentre trial that will randomise ~300 LAPC patients (chemotherapy ± OncoSil™) and is expected to form the basis of a Pre-market approval (PMA) application for US marketing clearance.

Cash runway to 1H18 could support CE Marking and full IDE approval by the FDA. Oncosil used $6.3m cash in FY17 and $2.4m in 4Q, closing the year with $8.0m. We assess the current cash level as sufficient to recruit and treat the 6 patients required for the European process and the 10 patients required in the US. MD Anderson is a large volume centre and its Principal Investigator has been involved with the OncoSil™ project for several years, so we are confident about Oncosil's ability to execute and make these early data packages available. Bear in mind that it takes 4 weeks between enrolment and implantation to start neoadjuvant chemotherapy; and the pre-specified follow-up time for both sets of regulators is 8 weeks post-implantation.

Pilot data a valuable inflection point. We would expect top-line data to print in Q1 of 2018 although the UK/AU data could come earlier than that depending on the pace of recruitment through August/September. For us, the most valuable aspect of these 20-pt datasets is the validation that OncoSil™ can been deployed safely in multiple cancer centres using a common protocol. After all, this work is the first clinical use of this product in a decade. Unfortunately, as the device is being investigated in combination with chemotherapy (standard of care gemcitabine/nab-paclitaxel) these early data will yield nothing specifically on the intrinsic, tumour-directed efficacy of OncoSil™ or its adverse event profile.

Key investment insight on OncoSil™

The opportunity for loco-regional radiotherapy in LAPC is undiminished, notwithstanding the failure of SIR-Spheres in treating liver metastases. We've had a number of incoming calls and conversations with investors asking whether Sirtex's disappointing results with their liver-directed cancer therapy (SIR-Spheres) in any way precludes OncoSil™ from being successful. It is a fair question. In the metastatic colorectal cancer (mCRC) setting, Sirtex's SIR-Spheres product (Yttrium-90 microspheres) did achieve statistically significant tumour control within the liver but that did not influence overall survival. The advice we have gathered on this question from consultants and from the clinical literature offer several lines of reasoning that support and differentiate the OncoPac-1 objective:

- **Understand the primary endpoint that the FDA accepted**. Local tumour control and quality of life are the important issues in LAPC[1]. The FDA supported the idea of OncoSil™ addressing progression free survival (LPFS) in the pancreas as primary endpoint, as opposed to overall survival (OS), which is included in OncoPac-1 as a secondary endpoint. The choice of primary endpoint reflects the pressing clinical challenges in early LAPC treatment: a) pre-operative therapies aimed at improving a patient's chance of undergoing margin-negative resection[2]; and b) local tumour control enhancing the synergistic effect of chemotherapy and radiotherapy combined in the treatment of unresectable locally advanced disease (ULAPC). New modalities are needed in LAPC that offer a rapid de-escalation of the primary tumour with good safety and low toxicity.
- **Goals of treatment are local disease control, symptom palliation and overall survival – in that order unfortunately**. LAPC patients have significant and distressing symptom burdens directly related to their primary malignancy including pain, pancreatic insufficiency, biliary obstruction, and early satiety/gastric outlet obstruction. These are all good reasons for targeting the primary tumour as a clinical objective with patient benefit. The recognition that some patients (with certain molecular and/or genetic characteristics) are more likely to have local-dominant progression rather than metastatic spread has also heightened interest in developing products for more effective local tumour control[3].
- **Understand the shortcomings of conventional chemoradiation as applied to pancreatic cancer**. Currently, the standard of care for patients who are unsuitable for surgery is the use of chemotherapy and/or radiotherapy (chemoradiation). A clear overall survival benefit for chemoradiation compared to chemotherapy alone has never been demonstrated. Chemotherapy and radiotherapy strategies struggle with LAPC because significant regions of the primary tumour are poorly vascularized and hypoxic. Poor blood supply precludes full access for systemically delivered drugs and the lack of oxygen denies radiation its full force (two thirds of its impact relies on reactive oxygen species generated by ionisation). External beam radiotherapy is also limited by the need to spare the surrounding organs and structures from toxicity. For this reason, a course of radiation might deliver 30-80 Gray of therapy to the tumour in daily sessions (or fractions) over a 5-6 week period. In recent years, stereotactic body radiation therapy (SBRT) has emerged, offering a way of delivering similar doses of radiation in 1-6 fractions with minimal dose to the surrounding tissues. SBRT is still delivering lower doses of radiation compared to OncoSil™ – 35-80 Gray[4] versus 100 Gray in a single procedure. The delivery of full doses of chemotherapy in parallel with SBRT has not been demonstrated to be safe and feasible compared with standard chemoradiation[5].

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[1] Balaban, E. P. *et al.* (2017) *Locally advanced, unresectable pancreatic cancer: ASCO clinical practice guideline summary*. J Oncol Pract. 13:265-269.
[2] Russo, S. and Wasif Saif, M. (2016) *Neoadjuvant therapy for pancreatic cancer: an ongoing debate*. Ther Adv Gastroenterol 9: 429–436.
[3] Iacobuzio-Donahue, C. A. *et al.* (2009) *DPC4 gene status of the primary carcinoma correlates with patterns of failure in patients with pancreatic cancer.* J Clin Oncol 27:1806-1813.
[4] Petrelli, F. *et al.* (2016) *Stereotactic body radiation therapy for locally advanced pancreatic cancer: a systematic review and pooled analysis of 19 trials* Int J Radiation Oncol Biol Phys, 2: 313-322.
[5] Phase III trials are testing FOLFIRINOX chemotherapy with or without SBRT for LAPC (ClinicalTrials.gov identifier NCT01926197) and will determine the safety and efficacy in terms of progression free survival for chemotherapy alone compared with the use SBRT.

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

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 in a single procedure, with limited toxicity. We think OncoSil™ can change clinical practice because it offers a potential solution to the number one problem reported by surgical oncologists who make the pancreas their focus: the ability to "de-escalate" primary tumours with a view to resection or treatment 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)

Balance sheet

- As at end FY17, Oncosil had ~$8.0m 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

- 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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