Date
03 August 2016

Theme
Company update

Company
Oncosil Medical (OSL)

WILSONS

IDE trial approval sets the scene for evidence development and commercialisation

The US Food and Drug Administration has granted Oncosil Medical the clearance it needs to start testing its medical device for the treatment of pancreatic cancer in US patients. The OncoPac-1 Study is a major set piece for Oncosil, designed to secure US market access and drive clinical adoption elsewhere. An Investigational Device Exemption (IDE) approval is a profoundly validating event for the company, in terms of proving that it can work well with major regulators to progress the development of medical device assets. The study itself is first rate from the design perspective – it's a tough study, it asks the correct clinical questions and it has a good chance of detecting any clinically meaningful signals. We maintain our price target at 48cps. We rate Oncosil a SPECULATIVE BUY.

Key points

FDA approval to commence US clinical trial. Months of collaborative work with the FDA has been rewarded with Oncosil Medical's clearance to start testing OncoSil™ in human subjects with locally advanced, unresectable pancreatic cancer. The OncoPac-1 study is the company's major clinical set piece over the next 3-4 years, designed to secure US market access and drive adoption elsewhere. The study design is as we expected: starting with a 20 patient safety "run-in" phase, before opening up to a randomised, open-label, pivotal trial targeting 300 patients, which on our calculations is enough to assess the level of anticipated efficacy in a statistically meaningful way. The trial has chosen a clinically relevant comparator, too, in the gemcitabine/abraxane regimen, which is the US standard of care. The primary endpoint of local progression free survival (PFS) is a registrable outcome with supportive secondary measures including PFS, overall survival (OS) and pain relief.

Project costs and timing. The FDA has added a lot of value in informing Oncosil's approach to OncoPac-1 in terms of patient safety, physician/endoscopist training, tumour stratification, procedural contingencies and the objective measurement of endpoints. We are expecting good recruitment rates as a result and view a two-year estimated enrolment period as achievable. Primary and secondary endpoints may be assessable by 2019, supporting a US approval in 2021, which is consistent with our forecasts and valuation basis.

CE Mark next. Oncosil remains confident of near-term approval to start selling OncoSil™ in Europe. CE Mark, if attained, will provide both further technology validation and modest revenues. The decision to invite European centres to participate in OncoPac-1 is smart, enabling practitioners to try the product under the guidance of a controlled protocol and be participants in the academic exercise. If successful, OncoPac-1 could be a landmark study in interventional radiology for pancreatic adenocarcinoma.

Valuation. We use a risk-adjusted discounted cash flow model to value Oncosil. Our price target is set with reference to our DCF valuation. See p.3 of this report for a summary of important risks to consider in assessing the investment merits of Oncosil. Oncosil remains a Speculative stock with a high risk/return profile. Un-risked valuation (three-year view, clinically de-risked) is $2.75 per share.

Recommendation	**BUY**
12-mth target price (AUD)	**$0.48**
Share price @ 05-Dec-12 (AUD)	$0.17
Forecast 12-mth capital return	193.2%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	**193.2%**
Market cap	$77m
Enterprise value	$68m
Shares on issue	464m
Sold short	0.0%
ASX 300 weight	n/a
Median turnover/day	$0.1m

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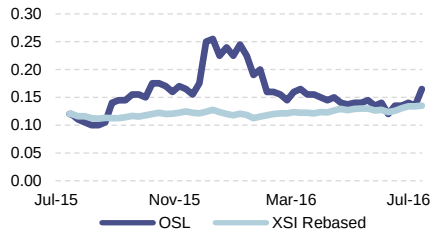
12-mth price performance ($)



	1-mth	6-mth	12-mth
Abs return (%)	17.9	-26.7	37.5
Rel return (%)	9.9	-40.0	23.8

Key changes

		25-Jul	After	Var %
NPAT:	**FY16F**	-4.4	-4.4	0.0%
norm	**FY17F**	-11.7	-11.7	0.0%
($m)	**FY18F**	-9.4	-9.4	0.0%
EPS:	**FY16F**	-1.2	-1.2	0.0%
norm	**FY17F**	-2.5	-2.5	0.0%
(cps)	**FY18F**	-1.9	-1.9	0.0%
DPS:	**FY16F**	0.0	0.0	0.0%
(cps)	**FY17F**	0.0	0.0	0.0%
	FY18F	0.0	0.0	0.0%
Price target:		0.48	0.48	0.0%
Rating:		**BUY**	**BUY**	

Price target	Valuation	Price target
WACC (%)	14	
Tg (%)	4	
NPV fcst FCF	53	
NPV perpetuity	139	
Net debt/(cash)	-5	
Valuation ($m)	197	
DCF ($/share)		0.38
HCC option ($/share)		0.11

Key assumptions								
Year-end June (AUD)	**FY13A**	**FY14A**	**FY15A**	**FY16F**	**FY17F**	**FY18F**	**FY19F**	**FY20F**
Revenue growth (%)	-100.0					81.5	370.1	77.7
EBIT growth (%)	-104.9	382.6	-35.9	48.0	162.6	-18.2	-32.3	-117.8
NPAT growth (%)	-105.1	379.7	-31.7	53.8	163.6	-19.1	-33.1	-120.0
EPS growth (%)	**-101.9**	**139.6**	**-40.4**	**46.8**	**109.9**	**-25.9**	**-33.1**	**-119.6**
EBIT/sales (%)					-1,166.8	-525.6	-75.7	7.6
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**	**-31.3**	**-72.2**	**-66.3**	**-50.2**	**8.3**
ROE (%)	**-14.5**	**-34.7**	**-41.4**	**-35.5**	**-87.2**	**-220.7**	**-202.9**	**29.3**

Price target ($/share)	**0.48**
Un-risked 3-yr val ($/sh)	**2.75**

Interims ($m)				
Half-year (AUD)	**Dec 14**	**Jun 15**	**Dec 15**	**Jun 16**
	1HA	**2HA**	**1HA**	**2HE**
Sales revenue	0.0	0.0	0.0	0.0
EBITDA	-2.5	-0.6	-1.8	-2.7
EBIT	-2.5	-0.6	-1.8	-2.7
Net profit	**-2.5**	**-0.4**	**-1.8**	**-2.7**
Norm EPS	**-0.7**	**-0.1**	**-0.5**	**-0.7**
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)	**FY15A**	**FY16F**	**FY17F**
Net debt	-2.5	-8.6	-11.9
Net debt/equity (%)	<0	<0	<0
Net debt/EV (%)	**<0**	**<0**	**<0**
Current ratio (x)	16.6	35.5	40.0
Interest cover (x)	19.9	74.6	>99
Adj cash int cover (x)	**2.4**	**75.2**	**>99**
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)				
	FY15A		**FY16F**	
	Rep	**Norm**	**Rep**	**Norm**
Sales revenue	0	0	0	0
EBIT	-3.0	-3.0	-4.5	-4.5
Net profit	**-2.9**	**-2.9**	**-4.4**	**-4.4**
Notional earn	0.0	0.0	0.0	0.0
Pref/conv div	0.0	0.0	0.0	0.0
Profit for EPS	**-2.9**	**-2.9**	**-4.4**	**-4.4**
Diluted shrs (m)	355	355	372	372
Diluted EPS (c)	**-0.8**	**-0.8**	**-1.2**	**-1.2**

Returns				
	FY15A	**FY16F**	**FY17F**	**FY18F**
ROE (%)	-30	-43	-77	-78
ROIC (%)	-31	-67	-169	>999
Incremental ROE	294	-236	-147	-73
Incremental ROIC	125	45	<-999	-30

Profit and loss ($m)								
Year-end June (AUD)	**FY13A**	**FY14A**	**FY15A**	**FY16F**	**FY17F**	**FY18F**	**FY19F**	**FY20F**
Sales revenue	0.0	0.0	0.0	0.0	1.0	1.8	8.6	15.3
EBITDA	-1.0	-4.7	-3.0	-4.4	-11.7	-9.6	-6.5	1.2
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**	**-4.5**	**-11.8**	**-9.6**	**-6.5**	**1.2**
Net interest expense	-0.1	-0.2	-0.2	-0.1	-0.1	-0.2	-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**	**-4.4**	**-11.7**	**-9.4**	**-6.3**	**1.3**
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**	**-4.4**	**-11.7**	**-9.4**	**-6.3**	**1.3**

Cash flow ($m)								
Year-end June (AUD)	**FY13A**	**FY14A**	**FY15A**	**FY16F**	**FY17F**	**FY18F**	**FY19F**	**FY20F**
EBITDA	-1.0	-4.7	-3.0	-4.4	-11.7	-9.6	-6.5	1.2
Interest & tax	-0.1	-0.2	2.8	0.0	-0.1	-0.2	-0.2	-0.1
Working cap/other	0.6	-1.4	0.1	0.1	0.4	10.5	-0.4	-0.3
Operating cash flow	**-0.5**	**-6.4**	**-0.2**	**-4.3**	**-11.5**	**0.7**	**-7.1**	**0.8**
Maintenance capex	0.0	0.0	0.0	-0.1	-0.2	-0.2	-0.2	-0.2
Free cash flow	**-0.5**	**-6.4**	**-0.2**	**-4.5**	**-11.7**	**0.5**	**-7.3**	**0.6**
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	0.0	0.0	0.0	0.0	0.0
Cash flow pre-financing	**-0.7**	**-11.1**	**-0.2**	**-4.5**	**-11.7**	**0.5**	**-7.3**	**0.6**
Funded by equity	1.8	10.3	0.0	10.5	15.0	0.0	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	-6.1	-3.3	-0.5	7.3	-0.6

Balance sheet summary ($m)								
Year-end June (AUD)	**FY13A**	**FY14A**	**FY15A**	**FY16F**	**FY17F**	**FY18F**	**FY19F**	**FY20F**
Cash	3.5	2.7	2.5	8.6	11.9	12.4	5.1	5.7
Current receivables	0.0	0.1	0.1	1.0	0.8	0.8	2.2	3.1
Current inventories	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.2
Net PPE	0.0	0.0	0.1	0.2	0.3	0.5	0.6	0.8
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	4.1	4.1	4.1	4.1	4.1
Total assets	**6.2**	**12.3**	**7.4**	**13.9**	**17.2**	**17.8**	**12.2**	**13.9**
Current payables	0.1	0.0	0.2	0.3	0.3	0.4	1.1	1.5
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	10.1	9.1	8.1
Total liabilities	**0.2**	**0.1**	**0.4**	**0.4**	**0.4**	**10.5**	**10.2**	**9.6**
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**	**13.5**	**16.8**	**7.4**	**2.0**	**4.3**
Total funds employed	**6.1**	**12.2**	**7.0**	**13.5**	**16.8**	**7.4**	**2.0**	**4.3**

Oncosil Medical Limited (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™ is an attractive product concept on account of its "single treatment" nature and dose intensity. We think the product deserves "accelerated review" status with the US Food and Drug Administration and will find good adoption by interventional radiologists, if approved.

Revenue drivers

- Pricing and reimbursement
- Market penetration (new clinical centres/hospitals, physician acceptance)
- New markets (geographical, clinical indications)

Balance sheet

- As at the Mar-16q, Oncosil had ~$14.4m in cash and no debt.

Margin drivers

- Gross margins sustainable at 80% or better
- Although SG&A structure is yet to evolve, Wilsons est. long-term rates of ~40-50% achievable
- Reimbursement outcomes (pricing)

Board

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

Key issues/catalysts

- CE Marking and European marketing
- Clinical trial design and FDA approvals
- Clinical trial execution
- Potential for commercial partnering interest over the next few years

Management

- Daniel Kenny (CEO)
- Ashish Soman (CMO)
- Charles Rowland (President – US Operations)
- Natalie Ruffles (VP Clinical)
- David James (VP Manufacturing)

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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Recommendation structure and other definitions

Definitions at wilsonsadvisory.com.au/Disclosures.

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