ONCOSIL MEDICAL (OSL)

Wilson HTM EQUITIES RESEARCH

BUY | HOLD | SELL

Company update

On the cusp in Europe

Oncosil Medical has set a November time frame for a decision on CE Marking, which if granted, can facilitate market access in Europe and other jurisdictions. The company has also related other positive operational developments, working towards making their product OncoSil™ available for the treatment of locally advanced pancreatic and liver cancers, if approved. Whilst regulatory outcomes are always difficult to predict, Oncosil appears well placed, at least from the quality assurance and manufacturing perspectives, having gained appropriate quality certifications earlier this year. We rate Oncosil Medical a SPECULATIVE BUY and maintain our 35 cps price target.

Key points

European regulatory processes to deliver a pivotal channel check on OncoSil™ – last week Oncosil Medical met with its Notified Body in the UK, as part of their process seeking a CE Mark designation for their medical device OncoSil™. CE Marking can lead to European marketing approvals and first sales revenue. As such, the review (and particularly its clinical evaluation component) is the first detailed, independent assessment that the OncoSil™ medical device has undergone. A decision is expected in November.

Risks and outcomes – regulatory actions such as this are fundamentally unpredictable for investors; as Notified Bodies often ask manufacturers for additional and/or clarifying information. Typically, device manufacturers are required to demonstrate the safety and performance of their device (conformity with claims). The stage of a clinical investigation for CE marking a medical device may therefore be compared with Phase II trials in drug development, where evidence of clinical activity, rather than statistically significant evidence of efficacy, is sought. That said, the European regulators are moving towards higher clinical evidence requirements, especially for higher risk (Class III) medical devices. Oncosil's data package comprises both pre-clinical and clinical investigations conducted in pancreatic and liver cancer subjects. A pivotal Phase III trial is planned for next year, with US registration as its goal.

Valuation – our risked DCF model implies a 35 cps target price on a fully diluted basis. Equity value could re-rate as the company passes quality and evidence gates: CE Mark in Q4; US pivotal trial design approval by the FDA in Q4; first commercial sales to EMEA in 2016. Our de-risked valuation for Oncosil is approximately 100 cps (upside case).

Risks and catalysts

Catalysts: a) CE Mark; b) FDA trial guidance; c) EU marketing approval and first sales. **Risks**: a) access to capital; b) clinical trial design risk; c) regulatory risks; d) product safety/quality/logistics risks; e) sector sentiment.

12-mth target price (AUD)	**$0.35**
Share price @ 13-Oct-15 (AUD)	$0.16
Forecast 12-mth capital return	117.4%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	**117.4%**
Market cap	$58m
Enterprise value	$39m
Shares on issue	360m
Sold short	0.2
ASX 300 weight	n/a
Median turnover/day	$0.1m

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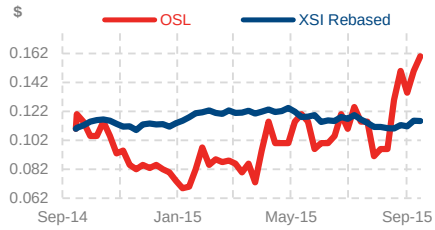
12-mth share price performance



	1-mth	6-mth	12-mth
Abs return (%)	39.1	83.9	45.5
Rel return (%)	34.8	89.6	40.5

Year-end June (AUD)	FY14A	FY15A	FY16F	FY17F	FY18F
NPAT rep ($m)	-4.2	-2.9	-6.1	-9.9	-8.5
NPAT norm ($m)	-4.2	-2.9	-6.1	-9.9	-8.5
Consensus NPAT ($m)					
EPS norm (cps)	-1.4	-0.8	-1.6	-2.2	-1.9
EPS growth (%)	-139.6	40.4	-97.4	-35.4	13.4
P/E norm (x)	-11.8	-19.7	-10.0	-7.4	-8.5
EV/EBITDA (x)	-8.3	-13.0	-6.4	-3.9	-4.6
FCF yield (%)	-11.1	-0.4	-11.1	-18.9	2.4
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, WHTM estimates, S&P Capital IQ

KEY CHANGES		06-Oct	After	Var %
NPAT:	**FY16F**	-6.1	-6.1	0.0%
norm	**FY17F**	-9.9	-9.9	0.0%
($m)	**FY18F**	-8.5	-8.5	0.0%
EPS:	**FY16F**	-1.6	-1.6	0.0%
norm	**FY17F**	-2.2	-2.2	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:		0.35	0.35	0.0%
Rating:		**BUY**	**BUY**	

PRICE TARGET

	Valuation	Price Target
WACC (%)	14	
Tg (%)	4	
NPV Fcst FCF	21	
NPV Perpetuity	94	
Net debt/(Cash)	-5	
Valuation ($m)	120	
DCF ($/share)		0.24
HCC option ($/share)		0.11
Price target ($ /share)		**0.35**
Un-risked valuation		**1.00**

INTERIMS ($m)

Half-year (AUD)	Dec 14 1HA	Jun 15 2HA	Dec 15 1HE	Jun 16 2HE
Sales revenue	0.0	0.0	0.7	0.8
EBITDA	-2.5	-0.6	-1.7	-4.4
EBIT	-2.5	-0.6	-1.7	-4.4
Net profit	**-2.5**	**-0.4**	**-1.7**	**-4.4**
Norm EPS	**-0.7**	**-0.1**	**-0.5**	**-1.1**
EBIT/sales (%)			-256.1	-586.9
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	-18.4	-7.5
Net debt/equity (%)	<0	<0	<0
Net debt/EV (%)	**<0**	**<0**	**<0**
Current ratio (x)	16.6	33.0	14.8
Interest cover (x)	19.9	78.5	33.1
Adj cash int cover (x)	**2.4**	**82.7**	**36.4**
Debt/cash flow (x)	0.0	0.0	0.0
Net debt (cash)/share ($)	<0	<0	<0
NTA/share ($)	0.0	0.1	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	1	1
EBIT	-3.0	-3.0	-6.2	-6.2
Net profit	**-2.9**	**-2.9**	**-6.1**	**-6.1**
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**	**-6.1**	**-6.1**
Diluted shrs (m)	355	355	380	380
Diluted EPS (c)	**-0.8**	**-0.8**	**-1.6**	**-1.6**

RETURNS

	FY15A	FY16F	FY17F	FY18F
ROE (%)	-30.1	-48.0	-73.3	-201.1
ROIC (%)	-30.6	-193.6	-1,252.6	154.3
Incremental ROE	293.8	-103.1	-486.0	-14.4
Incremental ROIC	125.0	46.6	164.8	-23.9

KEY ASSUMPTIONS

Year-end June (AUD)	FY13A	FY14A	FY15A	FY16F	FY17F	FY18F	FY19F	FY20F
Revenue Growth (%)	-100.0				41.4	54.0	228.2	50.0
EBIT Growth (%)	-104.9	382.6	-35.9	103.3	65.0	-14.9	-38.8	-121.9
NPAT Growth (%)	-105.1	379.7	-31.7	111.3	62.1	-13.4	-39.7	-123.6
EPS Growth (%)	**-101.9**	**139.6**	**-40.4**	**97.4**	**35.4**	**-13.4**	**-39.7**	**-123.6**
EBIT / Sales (%)				-431.4	-503.5	-278.1	-51.9	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**	**-50.2**	**-118.5**	**-106.1**	**-76.3**	**14.8**
ROE (%)	**-14.5**	**-34.7**	**-41.4**	**-59.4**	**-180.7**	**366.7**	**164.9**	**-62.1**

PROFIT AND LOSS ($m)

Year-end June (AUD)	FY13A	FY14A	FY15A	FY16F	FY17F	FY18F	FY19F	FY20F
Sales revenue	0.0	0.0	0.0	1.4	2.0	3.1	10.2	15.3
EBITDA	-1.0	-4.7	-3.0	-6.1	-10.1	-8.6	-5.2	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**	**-6.2**	**-10.2**	**-8.7**	**-5.3**	**1.2**
Net interest expense	-0.1	-0.2	-0.2	-0.1	-0.3	-0.1	-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**	**-6.1**	**-9.9**	**-8.5**	**-5.2**	**1.2**
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**	**-6.1**	**-9.9**	**-8.5**	**-5.2**	**1.2**

CASH FLOW ($m)

Year-end June (AUD)	FY13A	FY14A	FY15A	FY16F	FY17F	FY18F	FY19F	FY20F
EBITDA	-1.0	-4.7	-3.0	-6.1	-10.1	-8.6	-5.2	1.2
Interest & tax	-0.1	-0.2	2.8	-0.1	-0.3	-0.1	-0.1	-0.1
Working cap/other	0.6	-1.4	0.1	0.2	-0.2	10.3	-0.3	-0.4
Operating cash flow	**-0.5**	**-6.4**	**-0.2**	**-6.0**	**-10.7**	**1.6**	**-5.7**	**0.8**
Maintenance capex	0.0	0.0	0.0	-0.4	-0.2	-0.2	-0.2	-0.2
Free cash flow	**-0.5**	**-6.4**	**-0.2**	**-6.4**	**-10.9**	**1.4**	**-5.9**	**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**	**-6.4**	**-10.9**	**1.4**	**-5.9**	**0.6**
Funded by equity	1.8	10.3	0.0	17.5	0.0	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	-11.1	10.9	-1.4	5.9	-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	18.4	7.5	8.9	3.0	3.5
Current receivables	0.0	0.1	0.1	0.2	1.0	1.0	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	0.4	0.6	0.7	0.9	1.0
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	0.0	0.0	0.0	0.0	0.0
Total assets	**6.2**	**12.3**	**7.4**	**18.9**	**9.1**	**10.6**	**6.2**	**7.8**
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	0.3	0.3	10.3	9.3	8.3
Total liabilities	**0.2**	**0.1**	**0.4**	**0.6**	**0.6**	**10.7**	**10.3**	**9.8**
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**	**18.4**	**8.5**	**0.0**	**-4.2**	**-2.0**
Total funds employed	**6.1**	**12.2**	**7.0**	**18.4**	**8.5**	**0.0**	**-4.2**	**-2.0**

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. OncoSilTM provides a means of irradiating tumours from the inside, using microparticles impregnated with the radioactive isotope Phosphorus-32. OncoSilTM is expected to be granted CE Mark this year and be the subject of a large clinical trial in the US next year. We estimate a US$250m sales opportunity in the major pancreatic cancer markets.

INVESTMENT THESIS

OncoSilTM 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 FDA 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 1HFY15 result, Oncosil had ~$7m in cash and no debt

MARGIN DRIVERS

- Gross margins sustainable at 80% or better
- Although SG&A structure is yet to evolve WHTMe long-term rates of ~40-50% achievable
- Reimbursement

BOARD

- Roger Aston (Chairman)
- Daniel Kenny (Managing Director)
- Martin Rogers (Non-executive Director)

KEY ISSUES/CATALYSTS

- CE Marking and European marketing
- Clinical trial design and FDA approvals

MANAGEMENT

- Daniel Kenny (CEO)
- Ashish Soman (CMO)
- Natalie Ruffles (VP Clinical)
- Aoifa Brogan (VP Regulatory)
- David James (VP Manufacturing)

RISK TO VIEW

- Outlook depends on quality of evidence flowing from clinical trials
- Regulatory risks including manufacturing and quality
- Product safety
- Competitive risks in a busy oncology technology market

CONTACT DETAILS

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Recommendation structure and other definitions

Definitions at http://www.wilsonhtm.com.au/Disclosures

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Disclosure of interest. Oncosil Medical Limited

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