

# Oncosil takes the money ahead of key milestones

Oncosil Medical has announced an opportunistic funding top-up of \$10m while waiting for two key milestones. The company expects to start selling its brachytherapy device for the treatment of pancreatic cancer this year, once approved by the European regulator. A well-designed, large clinical trial is also anticipated in the USA, commencing 2016, should the FDA grant approval. Additional capital is required to support the company through to profitability, although non-dilutive alternatives could present themselves over the next few years, if its asset attracts interest from commercial partners. We maintain a SPECULATIVE BUY rating. Price target unchanged at 50cps.

# **Key points**

Oncosil Medical has announced a surprise \$10m private placement priced at 22cps. This was an attractively priced if small offering to the institutional market, which was placed ahead of two short-term price catalysts for the stock: a) the pending European marketing approval (CE Mark) for its product OncoSil<sup>TM</sup>; and b) the FDA's potential approval of Oncosil's plans to commence a registration-directed clinical trial, involving clinical sites in the USA.

Additional capital is required to fully prosecute the global trial and initial commercialisation. Oncosil reported \$5.8m cash as at the end of Dec-15, having recorded cash expenses of approximately \$3m over the 1HFY16 period (offset by a \$1.5m tax refund). Although a first product launch should follow immediately after CE Marking (which could occur at any time now), we expect sales will be modest initially. Oncosil's clinical trial is the company's major set piece over the next three years - likely to recruit around 250 patients over a two-year enrolment phase, with top-line data potentially available in 2018. The trial has been designed to form the basis for a Premarket Authorisation (PMA) submission to the FDA, and as such contemplates a high enough evidence level to concurrently support approval, clinical adoption, successful reimbursement outcomes and sales.

Trial execution a catalyst for attracting commercial interest, possibly funding. OncoSil<sup>TM</sup> is most likely to be commercialised in the USA via collaboration with a larger medical device or interventional radiology partner. We understand that several high profile clinical sites are being targeted, which may help attract partnering interest to the OncoSil<sup>TM</sup> program. An early partnering transaction could of course obviate the need for additional equity capital entirely - providing upside to our forecast and valuation (development risk reduction, non-dilutive R&D capital).

Valuation. No change. Our prior price target of 50cps was pre-emptively diluted for anticipated capital raising event(s) in FY16-17.

Investment view. OncoSil is an exciting early-stage medical device development company that investors with an appetite for risk should consider. Although the OncoSil™ product approach is not novel conceptually, it does potentially fill an important gap in current clinical practice. The recent addition of an experienced independent director is also a welcome development for the company. Important risks and catalysts are described on p.3 of this report.

12-mth target price (AUD)	\$0.50
Share price @ 11-Feb-16 (AUD)	\$0.19
Forecast 12-mth capital return	165.7%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	165.7%
Market cap	\$80m
Enterprise value	\$70m
Shares on issue	422m
Sold short	0.2%
ASX 300 weight	n/a
Median turnover/day	\$0.2m

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	1-mth	6-mth	12-mth
Abs return (%)	-17.4	65.2	163.9
Rel return (%)	-11.4	69.6	170.2

KEY CH	ANGES	21-Jan	After	Var %
NPAT:	FY16F	-6.1	-6.1	0.0%
norm	FY17F	-9.9	-9.9	N/A
(\$m)	FY18F	-8.5	-8.4	N/A
EPS:	FY16F	-1.6	-1.7	N/A
norm	FY17F	-2.2	-2.3	N/A
(cps)	FY18F	-1.9	-1.7	N/A
DPS:	FY16F	0.0	0.0	0.0%
(cps)	FY17F	0.0	0.0	0.0%
	FY18F	0.0	0.0	0.0%
Price tar	get:	0.50	0.50	0.9%
Rating:		BUY	BUY	



PRICE TARGET		
	Valuation	Price target
WACC (%)	14	
Tg (%)	4	
NPV fcst FCF	54	
NPV perpetuity	138	
Net debt/(cash)	-5	
Valuation (\$m)	197	
DCF (\$/share)		0.40
HCC option (\$/share)		0.11

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	62.4	-14.8	-40.3	-126.8
EPS growth (%)	-101.9	139.6	-40.4	104.8	35.8	-23.6	-40.3	-126.1
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	-42.6	-68.4	-59.3	-39.3	8.0
ROE (%)	-14.5	-34.7	-41.4	-49.0	-84.2	-204.5	-146.7	28.9

Price target (\$/share)	0.50
Un-risked 3-yr val (\$/sh)	2.75

INTERIMS (\$m)				
Half-year (AUD)	Dec 14	Jun 15	Dec 15	Jun 16
	1HA	2HA	1HE	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	-1.2
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

EBIT	-2.5	-0.6	-1.7	-4.4
Net profit	-2.5	-0.4	-1.7	-4.4
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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 STA	BILITY			
Year-end June (	AUD)	FY15A	FY16F	FY17F
Net debt		-2.5	-10.4	-13.7
Net debt/equity (%	6)	<0	<0	<0
Net debt/EV (%)		<0	<0	<0
Current ratio (x)		16.6	19.0	25.0

Year-end June (AUD)	FY15A	FY16F	FY17F	
Net debt	-2.5	-10.4	-13.7	
Net debt/equity (%)	<0	<0	<0	
Net debt/EV (%)	<0	<0	<0	
Current ratio (x)	16.6	19.0	25.0	
Interest cover (x)	19.9	78.5	35.1	
Adj cash int cover (x)	2.4	82.7	38.7	
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)							
	FY1	5A	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	367	367			
Diluted EPS (c)	-0.8	-0.8	-1.7	-1.7			
RETURNS							

	FY15A	FY16F	FY17F	FY18F
ROE (%)	-30.1	-70.2	-78.6	-79.8
ROIC (%)	-30.6	-193.6	-1,352.6	154.3
Incremental ROE	293.8	359.5	-97.5	-72.5
Incremental ROIC	125.0	46.6	164.8	-23.9

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	-0.2	-0.3	-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	-6.1	-9.9	-8.4	-5.0	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	-6.1	-9.9	-8.4	-5.0	1.3
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	-0.2	-0.3	-0.2
Working cap/other	0.6	-1.4	0.1	0.2	-0.3	10.5	-0.1	-0.1
Operating cash flow	-0.5	-6.4	-0.2	-6.0	-10.7	1.7	-5.6	0.9
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	1.5	-5.8	0.7
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	1.5	-5.8	0.7
Funded by equity	1.8	10.3	0.0	9.5	14.3	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

BALANCE SHEET SUMMARY (\$m)								
Year-end June (AUD)	FY13A	FY14A	FY15A	FY16F	FY17F	FY18F	FY19F	FY20F
Cash	3.5	2.7	2.5	10.4	13.7	15.2	9.4	10.1
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	10.9	15.4	17.0	12.6	14.4
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	10.4	14.7	6.3	2.3	4.7
Total funds employed	6.1	12.2	7.0	10.4	14.7	6.3	2.3	4.7



# **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<sup>TM</sup> provides a means of irradiating tumours from the inside, using microparticles impregnated with the radioactive isotope Phosphorus-32. OncoSil<sup>TM</sup> 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<sup>TM</sup> 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)

# **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 outcomes (pricing)

# **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

# **RISK TO VIEW**

- Currently the technology is 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 the Dec-15q, Oncosil had ~\$5.8m in cash and no debt

#### **BOARD**

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

#### **MANAGEMENT**

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

# **CONTACT DETAILS**

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