ONCOSIL MEDICAL (OSL)

Wilson HTM EQUITIES RESEARCH

BUY | HOLD | SELL

Company update

Thoughts on Oncosil's regulatory situation and outlook post management meeting

American and European regulatory agencies are still working with Oncosil Medical to map out the safest means of bringing the OncoSil™ medical device to market. While the program is delayed, both regulators have likely added much value to the asset. Improvements to study design and the clinical protocol may mean faster patient recruitment and higher quality evidence development at the back end of the trial. Separately, the financial impact of the delay looks reasonably well contained for now, with significant R&D trial expenses also deferred. Trial approval by the US Food and Drug Administration remains the most important near-term catalyst for the stock. We have modified our price target to 48cps but maintain a SPECULATIVE BUY rating.

Key points

IDE approval remains the most important near-term catalyst. We met with Oncosil management this week to discuss progress on its dual-track regulatory campaign. The US FDA is reviewing Oncosil's Investigational Device Exemption (IDE) proposal to conduct a large clinical trial of OncoSil™ for the treatment of pancreatic cancer. In Europe, regulators have spent almost a year assessing Oncosil's application to market its product for treating pancreatic and liver cancers. The IDE approval from the FDA significantly outweighs European approval from a valuation perspective, in our view. Oncosil's US trial sets out a pathway to obtaining higher level evidence for the device, which ultimately is the only basis for clinical adoption and reimbursement expectations in the major markets.

What does not kill development programs, makes them stronger. Both regulators appear to be making significant intellectual investments in assessing the safest means of testing OncoSil™ and making it available to patients. The review phase has taken longer than we expected, devoting much time to understanding and controlling the risks associated with the intended endoscopic delivery system, defining how best to stratify potential patients and tumour types, managing potential procedural complications and satisfying the regulators on other "what if" scenarios. Necessarily, this translates to clearer trial inclusion/exclusion criteria for the trial, greater clarity on the eligible patient population, robust clinical protocols, and if the device works as intended higher quality evidence.

Balance sheet. Oncosil reported ~$14m cash as 31 March. The regulatory delay will defer first revenues, but also delay the upfront R&D expenses associated with the US trial. We remain comfortable that Oncosil has sufficient capital to obtain its respective approvals, commence European sales and support its US trial, as we have modelled, from the first half of calendar 2017.

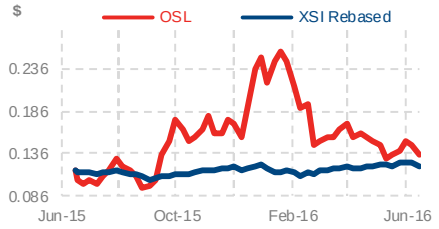
Valuation. Our revised target price of 48cps reflects the delay impact. We use a risk-adjusted discounted cash flow model to value Oncosil. Our price target is set with reference to our DCF valuation. See p.3 of this report for a summary of important risks to consider in assessing the investment merits of Oncosil. Oncosil remains a Speculative stock with a high risk/return profile.

Catalyst profile post-FDA approval. If the FDA allows Oncosil's IDE study in the coming months, then that should correspond to more regular positive new flow over the balance of 2016. Each hospital participating in Oncosil's trial will need to seek their own, individual Institutional Review Board approvals. We understand that the target trial sites comprise high impact cancer centres, whose association may further validate the OncoSil™ technology.

12-mth target price (AUD)	**$0.48**
Share price @ 14-Jun-16 (AUD)	$0.14
Forecast 12-mth capital return	258.4%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	**258.4%**
Market cap	$61m
Enterprise value	$53m
Shares on issue	454m
Sold short	0.0%
ASX 300 weight	n/a
Median turnover/day	$0.2m

Shane Storey
shane.storey@wilsonhtm.com.au
Tel. +61 7 3212 1351

12-mth share price performance



	1-mth	6-mth	12-mth
Abs return (%)	3.8	-22.9	17.4
Rel return (%)	5.3	-26.9	11.7

KEY CHANGES		17-Feb	After	Var %
NPAT:	**FY16F**	-6.1	-4.4	N/A
norm	**FY17F**	-9.9	-11.7	N/A
($m)	**FY18F**	-8.4	-9.4	N/A
EPS:	**FY16F**	-1.7	-1.2	N/A
norm	**FY17F**	-2.3	-2.5	N/A
(cps)	**FY18F**	-1.7	-1.9	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 target:		0.50	0.48	-4.2%
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 ($/share)		0.11
Price target ($/share)		**0.48**
Un-risked 3-yr valuation		**2.75**

INTERIMS ($m)

Half-year (AUD)	Dec 14 1HA	Jun 15 2HA	Dec 15 1HA	Jun 16 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

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**

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)

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

- 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

BALANCE SHEET

- As at the Mar-16q, Oncosil had ~$14.4m 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

Address: Suite 807, Level 8, 1 Alfred Street, Sydney, NSW 2000
Phone: +61 2 9223 3344
Web: www.oncosil.com.au

Disclosures and disclaimers

Recommendation structure and other definitions

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

Disclaimer

While Wilson HTM Ltd believes the information contained in this communication is based on reliable information, no warranty is given as to its accuracy and persons relying on this information do so at their own risk. To the extent permitted by law Wilson HTM Ltd disclaims all liability to any person relying on the information contained in this communication in respect of any loss or damage (including consequential loss or damage) however caused, which may be suffered or arise directly or indirectly in respect of such information. Any projections contained in this communication are estimates only. Such projections are subject to market influences and contingent upon matters outside the control of Wilson HTM Ltd and therefore may not be realised in the future.

The advice contained in this document is general advice. It has been prepared without taking account of any person's objectives, financial situation or needs and because of that, any person should, before acting on the advice, consider the appropriateness of the advice, having regard to the client's objectives, financial situation and needs. Those acting upon such information without first consulting one of Wilson HTM Ltd investment advisors do so entirely at their own risk. This report does not constitute an offer or invitation to purchase any securities and should not be relied upon in connection with any contract or commitment whatsoever. If the advice relates to the acquisition, or possible acquisition, of a particular financial product – the client should obtain a Product Disclosure Statement relating to the product and consider the Statement before making any decision about whether to acquire the product. This communication is not to be disclosed in whole or part or used by any other party without Wilson HTM Ltd's prior written consent.

Disclosure of interest. Oncosil Medical Ltd

The Directors of Wilson HTM Ltd advise that at the date of this report they and their associates have relevant interests in Oncosil Medical Limited. They also advise that Wilson HTM Ltd and Wilson HTM Corporate Finance Ltd A.B.N. 65 057 547 323 and their associates have received and may receive commissions or fees from Oncosil Medical Limited in relation to advice or dealings in securities. Some or all of Wilson HTM Ltd authorised representatives may be remunerated wholly or partly by way of commission.

In producing research reports, members of Wilson HTM Ltd Research may attend site visits and other meetings hosted by the issuers the subject of its research reports. In some instances the costs of such site visits or meetings may be met in part or in whole by the issuers concerned if Wilson HTM Ltd considers it is appropriate and reasonable in the specific circumstances relating to the site visit or meeting.

Please see disclosures at www.wilsonhtm.com.au/Disclosures. Disclosures applicable to companies included in this report can be found in the latest relevant published research.

Regulatory disclosures

This report was prepared solely by Wilson HTM Ltd. ASX did not prepare any part of the report and has not contributed in any way to its content. The role of ASX in relation to the preparation of the research reports is limited to funding their preparation, by Wilson HTM Ltd, in accordance with the ASX Equity Research Scheme. ASX does not provide financial product advice. The views expressed in this research report may not necessarily reflect the views of ASX. To the maximum extent permitted by law, no representation, warranty or undertaking, express or implied, is made and no responsibility or liability is accepted by ASX as to the adequacy, accuracy, completeness or reasonableness of the research reports.

Wilson HTM contact

Phone: 1300 655 015. Website: www.wilsonhtm.com.au.