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Oncosil Medical (OSL)

CE Mark Likely Imminent

Speculative
See key risks on Page 3 and Biotechnology Risk Warning on Page 5. Speculative securities may not be suitable for Retail Clients.

Recommendation
Buy (unchanged)
Price
$0.19
Target (12 months)
$0.30 (unchanged)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

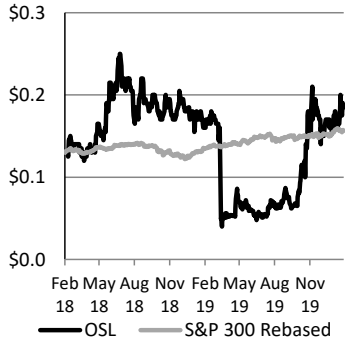
Expected Return	
Capital growth	**57.9%**
Dividend yield	**0.0%**
Total expected return	**57.9%**

Company Data & Ratios	
Enterprise value	**$112.8m**
Market cap	**$119.6m**
Issued capital	**630.7m**
Free float	**100%**
Avg. daily val. (52wk)	**$250,000**
12 month price range	**$0.02 - $0.21**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.16	0.14	0.17
Absolute (%)	15.63	37.04	8.82
Rel market (%)	11.49	32.10	-10.65

Absolute Price



SOURCE: IRESS

CE Mark Likely 1QCY2020

Years of work are now coming to a head for Oncosil with the likely imminent granting of the CE Mark for Oncosil therapy. During the course of the December quarter the British Standards Institute closed out all remaining clinical concerns. The company has since presented its Post Market Surveillance plan and Post Market Clinical Follow up both of which we understand were acceptable to the regulator. The essential component of these plans includes (but is not limited to) a register to monitor the long term progress of all patients receiving Oncosil therapy. The data emerging from the register will be owned by the company and may be used to support future marketing activities across all jurisdictions. The submission of the post market surveillance plan is normally a reliable indicator of a forthcoming approval.

We have previously estimated up to 85,000 new cases of pancreatic cancer annually in Europe with approximately 85% of these advanced and therefore inoperable at the time of diagnosis. The standard of care is a chemotherapy regime which delivers on average overall survival (OS) of 8.5 months with only 7-11% of cases down staged such that surgical cure becomes an option. In comparison OS in the per protocol group in the Panco study was at least 16 months with many of these patients undergoing curative surgery and still alive. The resection rate in the Panco trial was approximately 24%.

If the CE Mark is awarded, we believe it will represent the most significant event in the treatment of pancreatic cancer since the approval of the combination of Gemzar + Abraxane in 2013. Based on these survival benefits we believe the treatment regime for Oncosil will be well supported by physicians in the UK and major markets in Europe, Australia and throughout Asia (pending subsequent approvals in each country). Cash reserves at 31 December were $6.8m. Our forecast and valuation includes the dilutionary effect of a likely capital raise following the CE Mark.

Buy Maintained, Valuation $0.30

No changes to earnings forecasts and we maintain our Buy (Speculative) rating.

Earnings Forecast

June Year End	FY19	FY20e	FY21e	FY22e
Revenues	3.6	3.6	6.5	11.3
EBITDA $m	-8.7	-13.6	-18.7	-22.6
NPAT (underlying) $m	-8.5	-13.5	-18.6	-22.4
NPAT (reported) $m	-8.5	-13.5	-18.6	-22.4
EPS underlying (cps)	-1.4	-1.6	-2.3	-2.7
EPS growth %	nm	20%	38%	21%
PER (x)	nm	nm	nm	nm
FCF yield (%)	nm	nm	nm	nm
EV/EBITDA (x)	nm	nm	nm	nm
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	-81.0%	-28.9%	-65.5%	-366.7%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Next Horizon Is The US

Beyond CE Mark

Beyond the CE Mark in Europe Oncosil is likely to refocus its R&D programme on the US. The FDA granted a Humanitarian Use Designation for both intrahepatic (ICC) and distal cholangiocarcinoma (dCCA) in December 2019. The HUD is the first step towards a Humanitarian Device Exemption (HDE) which would allow marketing in the US.

ICC and dCCA are both forms of bile duct cancer. The function of the bile duct is to drain bile from the liver to the small bowel. Bile duct cancer is relatively rare with an addressable market of ~5,000 cases per year in the US. HDE's will only be granted for indication of less than 8,000 cases per year in the US.

In the short term we continue to expect the company to compete the HDE application for a dCCA only. This application will include the safety data from Panco study.

At the very least the HDE is likely to get the Oncosil therapy on market in the US and this is an important first step. Assuming that the HDE is awarded, OSL would be permitted to charge for the therapy albeit there will be a restriction on the number of devices made available. This is likely to limit any potential off label use of the product, and for certain OSL will not be permitted to market for off label use. Approvals in broader indications will require the formal IDE and pre market approval (PMA) process.

The key test for the HDE is the probable benefit–risk assessment. The standard of evidence is less than for a PMA and approvals take only 75 days once the appropriate data package has been assembled. This approval could move quickly once it become a focus.

These variants of CCA can be accessed, either percutaneously under CT guidance and/or via endoscopic ultrasonography. The OncoSil™ device has demonstrated that it can be safely and feasibly implanted into tumours using both these implantation techniques. The dose of OncoSil requires an accurate evaluation of the volume of the tumour to be injected and as these CCA variants are mass forming tumours they are amenable to OncoSil implantation.

Beyond Bile Duct Cancers

There are numerous options for further studies in the US including for the down staging of borderline surgical cases in pancreatic cancer and pilot studies in primary hepatic cancer. Based on the results of the PanCo study in Europe, we believe the most attractive opportunity for the US will be in the down staging of borderline resection cases in pancreatic cancer, for the reason that the overall survival benefit looks attractive. In the PanCo study many of the patients who were successfully down staged remain alive and on long term follow up. In Europe the indication under the CE Mark is likely to be quite broad and cover all pancreatic cancers including the borderline surgical cases.

The treatment landscape for pancreatic cancer continues to evolve with numerous studies under way at any given time. As we understand checkpoint inhibitors (including the market leading pembrozilumab from Merck) have not made a material difference the in the treatment of pancreatic cancer as highlighted by the recently completed literature review.

There are no changes to earnings and we maintain our Buy (Speculative) recommendation and valuation of $0.30.

Oncosil Limited

Oncosil Limited is a single product medical device company. Oncosil is a first in class intra-tumoral brachytherapy device seeking approval for the treatment of inoperable pancreatic cancer.

The initial target market for OncoSil™ is in pancreatic cancer where there remains a high unmet clinical need. It is estimated that each year there are more than new 85,000 cases in Europe and 46,000 new cases in the US. Five year survival is less than 1 in 20. The company also has aspirations to develop Oncosil for Primary Liver Cancer.

The company completed the PanCo study in 2019 and is currently seeking a CE Mark to commence commercialisation in Europe. The US FDA granted an Investigational Device Exemption (IDE) in August 2016. The trial design for a US approval study is yet to be discussed with the FDA. The company will be required to conduct at least 1 large phase III study in the US in order to gain approval.

KEY RISKS

Emerging therapy – Medical science continues to evolve and new therapies are constantly emerging. The oncology field attracts more R&D investment than most and consequently there are many new drugs in the pipeline. Despite this, based on our enquiries there are no late stage drugs in development for the treatment of Pancreatic Cancer. Clinical trials frequently produce good result at the phase II stage of development, however, these often fail to repeat in broader populations across multiple treatment centres. While the threat of an emerging therapy is constant, it is not imminent.

Medical Community is slow to adopt new therapy – Especially where the treatment is not supported by evidence from a large randomised controlled study. Consequently, our assumptions relating to adoption rates may overestimate potential revenues. Oncosil faces the additional challenge that it is the first brachytherapy for the treatment of pancreatic cancer.

Funding – Oncosil is likely to required further equity in order to complete the clinical program.

Clinical Risk – OSL has an investigational device exemption in the US for pancreatic cancer. Success in the clinic is required in order for the product to be marketed in the US. There is no guarantee that results from previous studies will be repeated in a broader, multi centre trial.

Other commercial risks - The validity of patents which protect the future income stream from OncoSil are yet to be tested. In addition, normal commercial risk relating to reliance on suppliers also apply. Oncosil Medical Ltd does not manufacture the Oncosil product and is entirely depended on a small number of hi-tech manufacturers for supply to its customer base. OncoSil is a highly toxic material. Its manufacture, storage, transport and use are each subject to regulatory requirements. OncoSil relies on various external parties to manage these risks in the normal course of their business.

Oncosil Medical
as at 10 February 2020

Recommendation	Buy, Speculative
Price	$0.19
Valuation (12 months)	$0.30

Table 1 - Financial summary

Profit & Loss (A$m)	FY18	FY19	FY20e	FY21e	FY22e
Year Ending June					
Dose sales (units)	-	-	11	205	890
Net revenue from product sales	-	-	0.6	3.5	8.3
COGS	-	-	- 0.1	-0.7	-1.7
Gross profit	-	-	0.5	2.8	6.6
GP margin				80%	80%
R&D incentive/Upfront receipts	4.4	3.6	3.0	3.0	3.0
Total revenues	**4.4**	**3.6**	**3.6**	**6.5**	**11.3**
Other expenses	**-13.1**	**-12.3**	**-17.1**	**-24.5**	**-32.2**
EBITDA	**-8.7**	**-8.7**	**-13.6**	**-18.7**	**-22.6**
Depreciation	0.0	0.0	0.0	0.0	0.0
Amortisation	0.0	0.0	0.0	0.0	0.0
EBIT	-8.7	-8.7	-13.6	-18.7	-22.5
Sundry income	0.2	0.2	0.1	0.1	0.1
Pre tax profit	-8.5	-8.5	-13.5	-18.6	-22.4
Tax expense	-	-	-	-	-
NPAT- normalised	-8.5	-8.5	-13.5	-18.6	-22.4
Net abnormal items	-	-	-	-	-
Reported NPAT	-8.5	-8.5	-13.5	-18.6	-22.4

Cashflow (A$m)	FY18	FY19	FY20e	FY21e	FY22e
Gross cashflow	-8.5	-7.7	-12.8	-16.0	-23.7
Net interest	0.1	0.2	0.1	0.1	0.1
Tax paid	0.0	0.0	0.0	0.0	0.0
Operating cash flow	-8.4	-7.5	-12.7	-15.9	-23.6
Maintenance capex	0.0	0.0	0.0	0.0	0.0
Capitalised clinical trial spend	0.0	0.0	0.0	0.0	0.0
Free cash flow	-8.4	-7.5	-12.7	-16.0	-23.6
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	15.6	0.0	50.0	0.0	0.0
Movement in investments	0.0	0.0	0.0	0.0	0.0
Dividends paid	0.0	0.0	0.0	0.0	0.0
Change in cash held	7.1	(7.5)	37.3	(16.0)	(23.6)
Cash at beginning of period	8.0	15.2	7.7	45.0	29.0
Cash at year end	15.2	7.7	45.0	29.0	5.4

Balance Sheet (A$m)	FY18	FY19	FY20e	FY21e	FY22e
Cash	15.2	7.7	45.0	29.0	5.4
Receivables	4.5	3.8	3.0	0.3	1.5
Short term investments	-	-	-	-	-
Other current assets	0.1	0.1	0.1	0.1	0.1
Property, Plant and Equipment	0.1	0.1	0.1	0.1	0.2
Total assets	19.9	11.7	48.2	29.6	7.1
Trade payables	1.6	0.8	0.8	0.8	0.8
Other provisions	0.1	0.2	0.2	0.2	0.3
Total Liabilities	1.7	1.0	1.0	1.0	1.0
Net Assets	18.2	10.7	47.2	28.6	6.1
Share capital	52.3	52.3	102.3	102.3	102.3
Retained earnings	(39.0)	(47.5)	(61.1)	(79.7)	(102.1)
Reserves	5.0	6.0	6.0	6.0	6.0
Shareholders Equity	18.2	10.7	47.2	28.6	6.1

Last sale 10/02/2020	0.190
Recommendation	Buy (Spec)
Issued Capital	630.7
Market Cap	119.8

Valuation Ratios (A$m)	FY18	FY19	FY20e	FY21e	FY22e
Reported EPS (cps)	-1.7	-1.4	-1.6	-2.3	-2.7
Normalised EPS (cps)	-1.7	-1.4	-1.6	-2.3	-2.7
EPS growth (%)	-11%	nm	20%	38%	0.2
PE(x)	**nm**	**nm**	**nm**	**nm**	**nm**
EV/EBITDA (x)	-13.0	nm	nm	nm	nm
EV/EBIT (x)	-13.0	nm	nm	nm	nm
NTA (cps)	2.9	1.7	5.7	3.5	0.7
P/NTA (x)	0.1	0.1	0.0	0.1	0.3
Book Value (cps)	2.9	1.7	5.7	3.5	0.7
Price/Book (x)	0.1	0.1	0.0	0.1	0.3
DPS (cps)	-	-	-	-	-
Payout ratio %	0%	0%	0%	0%	0%
Dividend Yield %	0.0%	0.0%	0.0%	0.0%	0.0%
Franking %	150%	0%	0%	0%	0%
FCF yield %	-712%	-636%	-811%	-1021%	-1508%
Net debt/Equity	0%	0%	0%	0%	0%
Net debt/Assets	0%	0%	0%	0%	0%
Gearing	net cash	net cash	net cash	net cash	net cash
Net debt/EBITDA (x)	n/a	n/a	n/a	n/a	n/a
Interest cover (x)	n/a	n/a	n/a	n/a	n/a

Dose sales (Units)	FY20e	FY21e	FY22e
Europe	11	175	800
USA	-	-	-
Australia/Asia Pacific	-	30	90
Total dose sales	**11**	**205**	**890**

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.

Such investments may carry an exceptionally high level of capital risk and volatility of returns.

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