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Oncosil Medical (OSL)

CE Mark Virtually Certain

Speculative
See key risks on Page 5 and Biotechnology Risk Warning on Page 7. Speculative securities may not be suitable for Retail Clients.

Recommendation
Buy (unchanged)
Price
$0.16
Valuation
$0.30 (previously $0.20)
Risk
Speculative

GICS Sector

Healthcare Equipment and Services

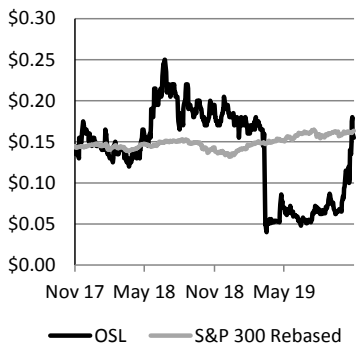
Expected Return	
Capital growth	**87.5%**
Dividend yield	**0.0%**
Total expected return	**87.5%**

Company Data & Ratios	
Enterprise value	**$91.7m**
Market cap	**$100.9m**
Issued capital	**630.7m**
Free float	**100%**
Avg. daily val. (52wk)	**$180,000**
12 month price range	**$0.02 - $0.21**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.07	0.07	0.19
Absolute (%)	127.9	138.5	-16.2
Rel market (%)	125.3	133.8	-31.6

Absolute Price



SOURCE: IRESS

BSI Issues Positive CE Mark Status Report

Recent announcements by the company regarding its steady progress with the submission of various data points to the European regulator (the British Standards Institute - BSI) are now coming to a head with the likely outcome that the company is virtually certain of receiving the CE Mark for its Oncosil therapy in the coming months.

Most recently Oncosil received a positive CE Mark Status report from BSI indicating that all remaining concerns with the external clinical and bio-statistical expert reports had been closed out. We understand this to mean there are no further questions regarding safety, protocol for use, mechanism of action and expected patient survival benefits. We outline the efficacy data in the body of this report, most of which has been previously reported.

The CE Mark process now moves to the final phase which is post market clinical follow up and surveillance. The company will shortly present its plans in this regard which is likely to consist of safety data from commercial sales of the device.

We expect the company will be awarded a CE Mark in the coming months with a broad indication for treatment of inoperable pancreatic cancer. The company is then likely to commence a limited roll out of the Oncosil therapy to a small number of hospitals in the UK, Europe and Australia.

Oncosil had notional cash as at 30 September of $9.2m which is sufficient to fund a limited launch, however, expansion of the sales and marketing function, plus the requirement for further clinical studies (required for registration in the US market) is likely to require a further capital raise which is built into the forecast for FY20.

Valuation Raised to $0.30

The valuation is raised to $0.30 and we retain our Buy (Speculative) recommendation. Changes to earnings in FY20 are immaterial. The forecast loss for FY21 is increased by approximately $6m due to the addition of marketing costs and ongoing R&D.

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

CE Mark Now Virtually Certain

The key data points from the 42 patients treated as per protocol in the Panco study are outlined below. The survival data from PanCo was first released at ASCO in June 2019. The comparative data on each of the efficacy measures is extracted from an extensive literature review conducted by the company as part of its more recent submission to the BSI. Each of the patients in Panco were diagnosed with local disease (i.e. no metastatic spread).

Figure 1 - Oncosil therapy - key efficacy measures vs retrospective literature review data

	Oncosil + Chemotherapy (per protocol)	95% CI	Chemotherapy only	Induction Chemo and Consolidation Chemoradiotherapy	All treatments
Overall Survival (months)	**16.0**	**11.1, NC**	**12.7**	**12.6**	**12.7**
Progression Free Survival (months)	9.3	7.2 - 12.2	6.6	7.6	7.6
Local disease control rate (week 24)	100%	91.6 - 100	71.3%	na	88.5%
Resection rates %	23.8%	12.1 - 39.5	7.7%	na	11.5%

SOURCE: COMPANY DATA

Based on this summary data we note the following key points:

Firstly, the state of the art therapy is defined by clinical practice guidelines as set out by the European Society of Medical Oncology (ESMO), American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN). The NCCN guidelines in particular offer numerous options for chemotherapy regimes.

Across all guidance, the standard for locally advanced pancreatic cancer are induction chemotherapy, chemotherapy and consolidation chemoradiotherapy.

OVERALL SURVIVAL

The gold standard for efficacy is overall survival benefit. In figure 1, overall survival in the Oncosil group was measured across 42 patients all of whom were implanted with Oncosil (being the treatment per protocol group). Relative to the standard of care the overall survival (OS) benefit is approximately 3.3 months. Even though the PanCo study was not randomised, the investigators estimate a pro-forma p-value (vs the patients in the literature review) of 0.001 which is highly statistically significant.

The extension in overall survival (being approximately a 26% extension from the SOC) is an outstanding outcome and the data is still maturing with 50% of the patients in the study still alive and in long term follow up. It is likely that there will be further updates on this survival data.

Progression free survival (PFS) is a commonly used proxy for overall survival in cancer trials (before the OS data has matured). Several drugs have been awarded accelerated approval by the FDA on the basis of a meaningful extension in PFS. These approvals are typically subject confirmatory studies and an overall survival benefit. In this case the PFS data is of limited significance as the OS data is available.

RESECTION RATE

The resection rate is a measure of patients first classified as inoperable, who are later reclassified/down staged and become suitable for surgery (following initial treatment).

Under the current standard of care (SOC), the resection rate is between 7 – 11%, relative to the Oncosil regime at ~24% (i.e. more than double SOC).

The resection rate is significant because of the survival benefit associated with the surgery. Key data from the literature review shows that patients undergoing surgical resection had significantly better survival than patients who did not. Median overall survival was 35.3 months vs 16.3 months and three year survival rates of 50% vs 11% ($p<0.001$).

Based on the PanCo study, the Oncosil regime appears to be a highly effective treatment for down staging inoperable tumours such that they become operable.

BASIS FOR RETROSPECTIVE LITERATURE REVIEW

The literature review has been a painstaking process completed by the company for the purposes of quantifying the clinical benefit of Oncosil therapy vs state of the art therapy. The literature review was necessary after the initial decision by the Clinical Oversight Committee (which makes recommendations to the British Standards Institute) that the Oncosil therapy regime delivered insufficient clinical benefit to warrant CE Mark approval.

While the Oncosil treatment regime has not (yet) been subject to the scrutiny of a large randomised clinical trial, the literature review in combination with the data from PanCo is nevertheless a sound basis for the proposed CE Mark approval. There are thousands of patients across dozens of studies included in the literature review and the survival benefit from Oncosil appears obvious.

Nevertheless, comparing results across clinical trials is always difficult because of disease complexity. Patients in the Panco study were treatment naïve to chemotherapy and radiotherapy and had local disease only (i.e. no metastatic disease). The difficulty in a retrospective analysis is to ensure that the patient groups are aligned as closely as possible. A second complicating factor is the age of some of the studies in the literature review relative to the progress in standard of care. The earliest studies in the literature review date back to the early 1980's, well before current chemotherapy regimes came to market.

In one of the more recent studies, 19 patients with local disease achieved median overall survival of 26 months after being treated with a new combination of leucovorin, S-1 (being an oral form of chemotherapy) and gemcitabine[1]. Relative to the OS data from the 54 studies in the literature review, the OS data from Saito et al is a standout and suggests that the patient group was less advanced than other studies.

DATA FROM A RANDOMISED STUDY MAY YET BE REQUIRED

It is for these key reasons that we expect further clinical trials may yet be required to provide confirmation of the overall survival benefit from the Oncosil therapy. Data from a larger randomised study is normally fundamental to support broad adoption, particularly in the United States.

PATH TO CE MARK

Oncosil has now received a positive status report from BSI following the Clinical Oversight Committee (COC) review meeting. The status report confirms that BSI has now completed the analysis of the data outlined above (and detailed in the company's announcement to the ASX on 29 October 2019) and closed out all concerns with regard to external clinical and bio-statistical experts.

The final part of the review is the post market clinical follow up (PMCF) and post market surveillance plan (PMS). As we understand:

[1] Saito et al, Investigational New Drugs April 2019, Volume 37, Issue 2 pp 338 – 344.

- The focus of these programmes is to ensure the safety data continues to be monitored post approval. It is reasonable to assume this data will come from commercial patients rather than clinical trials;
- The BSI does not require further clinical data to prove efficacy; and
- Once the CE Mark is awarded, the company may commence marketing Oncosil therapy across the EU, subject to any local safety requirements which normally requires facilities to be accredited for handling dangerous goods.

Assuming the CE Mark is awarded in the coming months, we expect OSL will first obtain a local approval in the UK followed by a roll out to a small number of hospitals (being those 4 hospitals which participated in the Panco study) as well as the hospitals in Australia which participated in the trial. We expect Oncosil will also launch is in Belgium, Germany, Italy and France.

FURTHER CLINICAL STUDIES

Oncosil already has an IDE for a clinical trial in the United States. The OncoPac-1 study completed enrolment of the first 10 patient cohort some time ago and we understand patients are on long term follow up. It has been some time since the company provided an update on their progress, but as far as we are aware this trial is ongoing.

Normally the AMA and NCCN require data from a large randomised clinical trial in order to support broad adoption of a new device in their guidelines. The FDA also normally requires this data for approval of a device. We await an update on the progress of OncoPac-1 and more broadly on the regulatory pathway for pancreatic cancer in the US.

In the interim, the company has been engaged with the FDA over the course of the last two years and recently obtained a Humanitarian Use Designation (HUD) for both intrahepatic (ICC) and distal cholangiocarcinoma (dCCA) – or bile duct cancer. Building on this success the company intends to apply for a humanitarian Device Exemption in dCCA which would allow the Oncosil therapy to marketed to this small patient population only.

Following the CE Mark, we expect the company's clinical trial focus to return to the US. The US is a more attractive commercial market than the EU (i.e. reimbursement is significantly higher), hence it is logical that any future randomised clinical trial should include recruitment sites from the US.

SUMMARY OF EARNINGS CHANGES

Figure 2 - Summary of earnings changes

	2020			2021		
	New	Old	% change	New	Old	% change
Revenues	3.6	3.7	-2%	6.5	7.3	-11%
EBITDA	-13.6	-13.4	2%	-18.7	-12.9	-45%
NPAT	-13.5	-12.9	5%	-18.6	-12.4	-50%
EPS	-1.6	-1.7	-3%	-2.3	-1.6	-41%

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

Revenues in FY20 represent mainly the R&D tax refund. First meaningful revenues from product sales are due in FY21.

We have also assumed an increase in the cost base from FY21 onwards consisting of clinical trials and marketing cost. The forecast allows for A$30m relating to a randomised study which we believe is required to support broad adoption in the US.

Following the announcement that the BSI has issued a positive CE Mark Status report, the key adjustment to the valuation model is a favourable adjustment to risk factor attached to future revenues, consequently our valuation is adjusted to $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 14 November 2019

Recommendation	Buy, Speculative
Price	$0.16
Valuation	$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	-10.5	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	-12.2	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 14/11/2019	0.160
Recommendation	Buy (Spec)
Issued Capital	630.7
Market Cap	100.9

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)	-10.5	nm	nm	nm	nm
EV/EBIT (x)	-10.5	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	0.0	0.2
Book Value (cps)	2.9	1.7	5.7	3.5	0.7
Price/Book (x)	0.1	0.1	0.0	0.0	0.2
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 %	-845%	-756%	-963%	-1213%	-1790%
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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