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Oncosil Medical (OSL)

UK Launch in FY19

Speculative
Refer to 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
$0.195
Valuation
$0.39 (unchanged)

GICS Sector

Healthcare Equipment and Services

Expected Return	
Capital growth	**100%**
Dividend yield	**0%**
Total expected return	**100%**

Company Data & Ratios	
Enterprise value	**$105.7m**
Market cap	**$121.7m**
Issued capital	**624.2m**
Free float	**100%**
Avg. daily val. (52wk)	**$233,000**
12 month price range	**$0.09 - $0.26**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.21	0.18	0.09
Absolute (%)	-7.32	5.56	108.79
Rel market (%)	-5.15	3.89	101.13

Commercialisation now a reality

The recent announcement that Oncosil has engaged IQVIA as Market Access and Reimbursement advisor is a clear signal that commercialisation of the Oncosil therapy is about to become a reality in markets outside the United States. The challenge now before the company is to promote uptake of the product without all the clinical data ideally required for broad adoption.

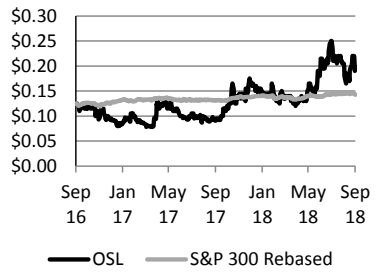
Following CE Mark, we expect Oncosil will be first launched in the UK and Germany. The level of reimbursement is yet to be determined in either jurisdiction. First commercial revenues are likely his fiscal year but not before 1 January 2019.

IQVIA (formerly Quintiles IMS) are a specialist healthcare consulting firm. Their role in the UK and across Europe will be to assist Oncosil to access pools of funding. In the UK, funding for new devices can be haphazard, particularly in the case of Oncosil where use of the product is not supported by evidence from a large randomised study or a NICE recommendation. **This note reviews the most recent clinical data which we regard as generally supportive of clinical adoption.**

Long term adoption will ultimately depend upon survival data from a large randomised study. The form of the study or studies is yet to be determined as the company awaits engagement with the regulators in Europe and the US before committing to a pivotal study design.

Oncosil has cash and receivables of $19.7m at 30 June 2018 – sufficient for nearly two years operating requirement assuming the cash burn rate moderates following the completion of recruitment in clinical trials. The company will require further funding – most likely in FY20, albeit this may come from the sale of rights to a strategic partner. The forecast assumes a transaction of this nature in FY19. In the absence of a cash injection from this theorised transaction, the company would most likely require further funding from shareholders and this may cause a downward adjustment to our valuation. We maintain our valuation at $0.39 and Buy recommendation.

Absolute Price



SOURCE: IRESS

Earnings Forecast

June Year End	FY18	FY19e	FY20e	FY21e
Revenues	4.4	43.4	9.2	21.7
EBITDA $m	-8.7	23.8	-11.8	-10.1
NPAT (underlying) $m	-8.5	24.3	-11.3	-9.6
NPAT (reported) $m	-8.5	24.3	-11.3	-9.6
EPS underlying (cps)	-1.7	4.0	-1.9	-1.6
EPS growth %	-11%	nm	-146%	-15%
PER (x)	nm	nm	nm	nm
FCF yield (%)	nm	nm	nm	nm
EV/EBITDA (x)	-12.1	4.4	-9.0	-10.5
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	-47.7%	56.1%	-37.8%	-46.6%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Preparing for commercial launch

We expect Oncosil therapy will be awarded the CE Mark later this year. We understand the product will be first launched in the UK and Germany.

In the UK, the initial use of the product will be dependent upon funding within each NHS Trust and certain discretionary funding available at regional levels within the NHS. Local knowledge and relationships will be key to accessing the discretionary funding in particular and this is where IQVIA will help. The four NHS Trusts which participated in the recent PanCo study are the obvious starting point as the treatment teams in those hospitals will have seen the product first hand. IQVIA will also assist in determining the product pricing.

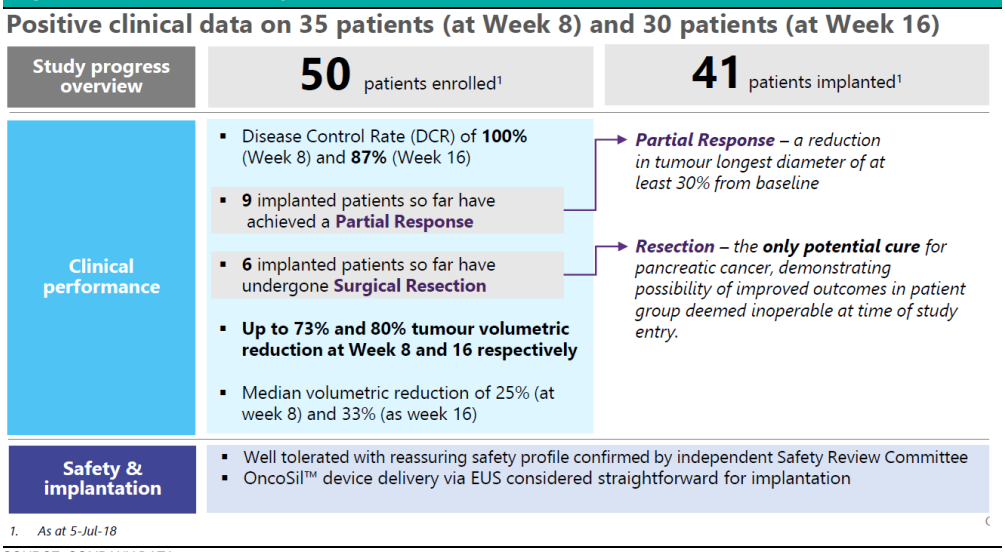
The CE Mark indication will most likely be for the treatment of all inoperable pancreatic cancers. We expect the company will have also requested an indication for the down staging of borderline resectable disease.

CLINICAL UPDATE

The key data points from the most recent clinical update (released 30 August 2018) are as follows.

The primary objective of the PanCo study was to control tumour growth.

Figure 1 - Clinical Summary from PanCo



SOURCE: COMPANY DATA

The PanCo study is fully enrolled. The final 10 patients in the trial were enrolled relatively quickly over a period of 2 months and we regard this enrolment rate is encouraging for future clinical adoption.

Of the 50 patients enrolled in the study, 41 patients received the Oncosil therapy. 9 patients did not receive Oncosil for a variety of reasons. Of the patients who have received therapy, 35 have reached at least week 8 and 30 have reached week 16 post implantation.

Patients will be followed for survival for 2 years or until death. We do not expect survival data from the study until at least 2020.

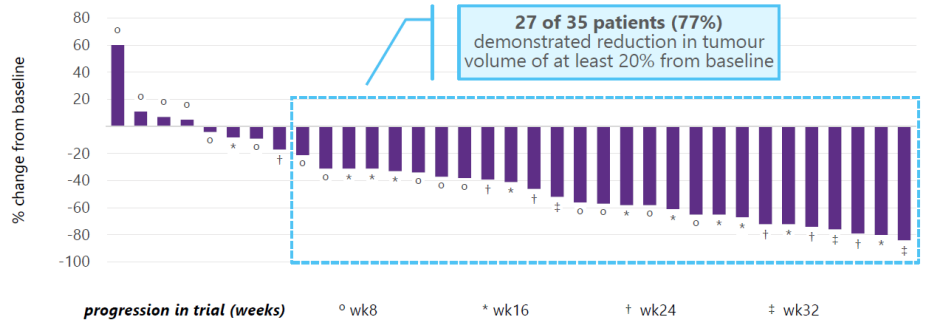
9 patients have achieved a partial response as measured under RECIST[1]. Of these patients 6 (i.e. 6 of 35 being 17%) have undergone surgical resection. Of the 6 surgical patients, 5 have achieved R0 surgical margins – which means there is no cancerous tissue in the areas abutting the site of the original tumour. This is highly encouraging data for

[1] RECIST 1.1 – standard method for assessment of change in tumour burden

future studies. In our view the company will consider a future trial to study the potential for down staging of borderline resection patients.

Figure 2 - Tumour volumetric reduction

Best tumour volumetric change in first 35 implanted patients



SOURCE: COMPANY DATA

There are 35 columns in figure 2, with each column representing an individual patient. Of these 35 patients most are at least 4 months post implant with 77% having achieve volumetric reduction of at least 20%.

The data on volumetric reduction is not included as a criteria for RECIST 1.1. The later uses longest tumour diameter as the key measurement criteria. In this case the RECIST data does appear to understate the efficacy of the Oncosil therapy in controlling the growth of the tumours. Ultimately the localised PFS and overall survival data will dictate the success of the therapy.

We note there is a definite skew of larger volumetric reductions to the longer dated patients, accordingly, it is reasonable to assume the volumetric reductions in the more recently implanted patients will continue to show improvement.

SURVIVAL DATA

35 of 35 patients remain alive at this point in time with the longest dated patients now at 32 weeks post treatment. Under the standard of care for the treatment of advanced pancreatic cancer, the average length of survival post treatment is ~8.5 months or 36 weeks. This comparative survival data is based on patients with metastatic disease and is the only benchmark available. As the data from PanCo matures over the coming months, we have no doubt it should influence reimbursement discussion in the initial markets where the product is launched.

SAFETY

The company reports the treatment is well tolerated. There are no serious adverse events related to the Oncosil therapy. Most importantly there is no adverse event related to leaching of the radioactive material outside of the pancreas.

PAIN SCORES

Oncosil is yet to release data on pain scores and quality of life, however, based on the tumour volumetric reduction. Pain score data – while not objective data are nevertheless meaningful for patients and their oncologists.

Over the next few months as all this data matures, based on current trends Oncosil is likely to have a compelling data package to put before payers in the UK and elsewhere. While this data package will not include data from a randomised, controlled, blinded study, there will be data from at least 60 patients with anecdotal survival data (50 in PanCo and a further 10 from the OncoPac study being recruited in the US).

FUTURE CLINICAL DIRECTION

Long term adoption will ultimately depend upon survival data from a large randomised study. The form of the study or studies is yet to be determined as the company awaits engagement with the regulators in Europe and the US before committing to a pivotal study design.

The data from the PanCo study is suggestive that Oncosil in combination with chemotherapy can control the progression of tumours within the pancreas, however randomised data is necessary to confirm the incremental effect of Oncosil over chemotherapy alone for overall survival. At some point the company will have to run this survival benefit study but it is probably not the first option.

We expect the company will use the data from the both the European and US trial in future discussions with regulators. The company has been silent on its intended regulatory pathway in the US beyond the current OncoPac1 trial.

Ideally the company will run further studies with the objective of obtaining an FDA approval in the shortest possible time frame. We speculate this trial may target borderline resection patients with the goal of downsizing tumours for surgery (as a surrogate marker). Alternatively the company may pursue a smaller randomised study not dissimilar to PanCo – except with a control arm. In this case the FDA may accept localised progression free survival or overall response rate as a surrogate marker of survival. We note that Merck's blockbuster Pemrolizumab obtained its first accelerated approval (in melanoma) based on overall response rate. Either way the absence of any breakthrough in the treatment of advance pancreatic disease for more than a decade is sufficient reason to pursue an accelerated approval, provided of course the clinical data is supportive.

FUNDING

Cash at 30 June 2018 was $15.2m plus $4.5m in receivables. Based on the most recent quarterly, the annualised cash burn is $11.6m, however, as the company is no longer recruiting patients in PanCo, the burn rate will most likely decline to the range of $6m to $8m for FY19.

The key factors affecting the timing of the next funding include:

- Commencement date for future clinical studies;
- Uptake on commercialisation in Europe together with the level of reimbursement; and
- Strategic partnership and licensing agreements – the company may consider the sale of rights in key jurisdictions including China or Japan as the most likely first candidates. Chinese interest in Australian healthcare assets is at an all time high and we note Sirtex and Mesoblast have both announced commercialisation partners for China in recent months.

Our model assumes $43m in commercialisation revenues from a partner in FY19. If this transaction does not eventuate, our valuation is likely to reduce by the dilutionary effect of a subsequent capital raise – probably in FY20.

There are no significant changes to our earnings at this time, our valuation remains $0.39 and we maintain our Buy (Speculative) recommendation.

Oncosil Limited

Oncosil Limited is a single product medical device company. Oncosil is a first in class intra-tumoral brachytherapy device seeking approval for pancreatic cancer using an administration procedure that has never been done before in the United States.

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.

PanCo and OncoPac-1 are the two studies which make up the Global Pancreatic Cancer Study program. It is a multicentre, international pivotal study investigating the use of Oncosil for the treatment advanced pancreatic cancer. The US FDA granted an Investigational Device Exemption (IDE) in August 2016. The trial design of subsequent studies has changed from our earlier research. The company has numerous options for follow up studies.

KEY RISKS

CE Mark –The CE Mark will allow OSL to commence marketing of OncoSil within the EU. The CE Mark will also serve as a precursor for approvals in other markets including Australia.

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. Our forecast also includes an assumption of a licence sale to a significant jurisdiction in FY19. Should this not occur, or the proceeds therefrom yield significantly less than we anticipate, it is likely the company would be required to raise additional capital from shareholders.

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 September 2018

Recommendation	Buy
Price	$0.195
Valuation	$0.39

Table 1 - Financial summary

Profit & Loss (A$m)	FY17	FY18	FY19e	FY20e	FY21e
Year Ending June					
Dose sales (units)	-	-	60	1,110	2,400
Net revenue from product sales	-	-	0.4	6.2	18.7
COGS	-	-	0.1	-1.2	-3.7
Gross profit	-	-	0.4	5.0	14.9
GP margin	50%	60%	80%	80%	80%
R&D incentive/Upfront receipts	3.4	4.4	43.0	3.0	3.0
Total revenues	**3.4**	**4.4**	**43.4**	**9.2**	**21.7**
Other expenses	**-10.8**	**-13.1**	**-19.6**	**-19.8**	**-28.0**
EBITDA	**-7.3**	**-8.7**	**23.8**	**-11.8**	**-10.1**
Depreciation	0.0	0.0	0.0	0.0	0.0
Amortisation	0.0	0.0	0.0	0.0	0.0
EBIT	-7.3	-8.7	23.8	-11.8	-10.1
Sundry income	0.3	0.2	0.5	0.5	0.5
Pre tax profit	-7.0	-8.5	24.3	-11.3	-9.6
Tax expense	-	-	-	-	-
NPAT- normalised	-7.0	-8.5	24.3	-11.3	-9.6
Net abnormal items	-	-	-	-	-
Reported NPAT	-7.0	-8.5	24.3	-11.3	-9.6

Cashflow (A$m)	FY17	FY18	FY19e	FY20e	FY21e
Gross cashflow	-8.6	-8.5	25.2	-11.8	-11.9
Net interest	0.2	0.1	0.5	0.5	0.5
Tax paid	0.0	0.0	0.0	0.0	0.0
Operating cash flow	-6.1	-8.4	25.7	-11.3	-11.4
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	-6.2	-8.4	25.7	-11.3	-11.5
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	1.0	15.6	0.0	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	(5.2)	7.1	25.7	(11.3)	(11.5)
Cash at beginning of period	9.8	8.0	15.2	40.9	29.6
Cash at year end	8.0	15.2	40.9	29.6	18.1

Balance Sheet (A$m)	FY17	FY18	FY19e	FY20e	FY21e
Cash	8.0	15.2	40.9	29.6	18.1
Other current assets	3.7	4.6	3.1	3.1	5.0
Property, Plant and Equipment	0.1	0.1	0.1	0.2	0.2
Total assets	11.9	19.9	44.1	32.9	23.3
Trade payables	1.5	1.6	1.6	1.6	1.6
Other provisions	0.1	0.1	0.1	0.1	0.1
Total Liabilities	1.7	1.7	1.7	1.7	1.7
Net Assets	10.2	18.2	42.4	31.2	21.6
Share capital	36.7	52.3	52.3	52.3	52.3
Retained earnings	(30.5)	(39.0)	(14.8)	(26.1)	(35.6)
Reserves	4.0	5.0	4.9	5.0	5.0
Shareholders Equity	10.2	18.2	42.4	31.2	21.6

Last sale 10/09/2018	0.195
Recommendation	Buy (Spec)
Issued Capital	624.2
Market Cap	121.7

Valuation Ratios (A$m)	FY17	FY18	FY19e	FY20e	FY21e
Reported EPS (cps)	-1.5	-1.7	4.0	-1.9	-1.6
Normalised EPS (cps)	-1.5	-1.7	4.0	-1.9	-1.6
EPS growth (%)	-28%	-11%	nm	-146%	-0.2
PE(x)	**nm**	**nm**	**nm**	**nm**	**nm**
EV/EBITDA (x)	-14.4	-12.1	4.4	-9.0	-10.5
EV/EBIT (x)	-14.4	-12.2	4.4	-9.0	-10.5
NTA (cps)	2.1	3.0	7.0	5.1	3.6
P/NTA (x)	0.1	0.1	0.0	0.0	0.1
Book Value (cps)	2.1	3.0	7.0	5.1	3.6
Price/Book (x)	0.1	0.1	0.0	0.0	0.1
DPS (cps)	-	-	-	-	-
Payout ratio %	0%	0%	0%	0%	0%
Dividend Yield %	0.0%	0.0%	0.0%	0.0%	0.0%
Franking %	97%	0%	0%	0%	0%
FCF yield %	-889%	-713%	2170%	-952%	-970%
Net debt/Equity	0%	0%	0%	0%	0%
Net debt/Assets	0%	0%	0%	0%	0%
Gearing	net cash	0%	0%	0%	0%
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)	FY19e	FY20e	FY21e
Europe	60	1,050	1,400
USA	-	-	700
Australia/Asia Pacific	-	60	300
Total dose sales	**60**	**1,110**	**2,400**

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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