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OncoSil Medical Ltd (OSL)

Enrolment Commences

Speculative
Refer to key risks on page 6 and Biotechnology Risk Warning on page 8. Speculative securities may not be suitable for retail clients.

Recommendation
Buy (unchanged)
Price
$0.08
Valuation
$0.39 (unchanged)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

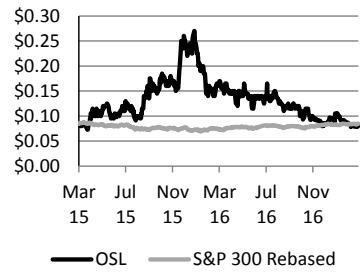
Expected Return	
Capital growth	**387%**
Dividend yield	**0.0%**
Total expected return	**387%**

Company Data & Ratios	
Enterprise value	**$26.7m**
Market cap	**$37.4m**
Issued capital	**468.5m**
Free float	**100%**
Avg. daily val. (52wk)	**$111,000**
12 month price range	**$0.076 - $0.185**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.09	0.08	0.16
Absolute (%)	-8.05	-3.61	-50.00
Rel market (%)	-8.21	-7.18	-62.97

Absolute Price



SOURCE: IRESS

First Patient Enrolled In OncoPac 1

OncoSil continues to make large strides towards the approval of its therapy for the treatment of locally advanced pancreatic cancer and has today announced the significant milestone of first patient enrolment in the pivotal Onco Pac 1 clinical trial.

The patient will be treated at the Monash Cancer Centre in Melbourne. Monash is one of a series of leading cancer treatment facilities to have confirmed participation in the trial. Further local and international patient enrolments are expected within weeks. The timing of this enrolment is consistent with our expectation of 1Q CY17.

The patient is the first in a total of 20 required to meet the supplemental data request (covering safety and efficacy) to secure the CE Mark. Regulators in Europe and the US have both requested this data. We theorise that enrolment should be completed by 30 June and the data to be compiled and ready for submission to BSI by 30 September 2017.

The company has previously announced the CE Mark will be granted subject to supplemental data supporting existing safety and clinical performance. In addition OSL has agreed to a post marketing clinical follow up programme.

First Revenues Probable In Calendar 2017

OncoSil therapy is first in class for the treatment of locally advanced pancreatic cancer, hence the supplemental data is highly relevant for all stakeholders. Assuming all goes well, we expect OSL will release the data from these 20 patients shortly after the CE Mark is granted.

We believe OncoSil remains on track to generate first revenues from the sale of product in calendar 2017 i.e. we expect there is a large patient group who will not meet the eligibility criteria for the trial, yet may still benefit from the therapy.

Changes to earnings forecasts are not material and we retain our Buy recommendation with a valuation of $0.39.

Earnings Forecast

June Year End	FY16	FY17e	FY18e	FY19e
Revenues	3.8	3.5	4.2	46.3
EBITDA $m	-5.0	-7.7	-10.8	29.4
NPAT (underlying) $m	-4.8	-7.2	-10.3	29.9
NPAT (reported) $m	-4.8	-7.2	-10.3	29.9
EPS underlying (cps)	-1.2	-1.5	-2.0	5.8
EPS growth %	-46%	-28%	-34%	nm
PER (x)	nm	nm	nm	nm
FCF yield (%)	nm	nm	nm	nm
EV/EBITDA (x)	-5.2	-3.4	-2.4	0.9
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	-33.8%	-102.0%	-75.9%	66.6%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Onco Pac 1 Enrolment Begins

The announcement of the first patient enrolment into OncoPac 1 continues the stream of news flow from OSL over the last 6 months.

Both the FDA and the European Regulator require safety and efficacy data from a 20 patient run in of the therapy. The Europeans will accept patient data from all sources, however the FDA will only accept data from patients treated in the US.

Patient enrolment has now commenced in Australia and we expect first enrolments in the UK and US are imminent. The supplemental data required for the CE Mark will be ready first, followed shortly thereafter by the data for the FDA.

The half life of OncoSil therapy is 14 days, with all traces of radioactivity gone at 3 months. Any adverse event emerging after this time frame is highly unlikely to be connected with the OncoSil therapy. For these reasons the run in group(s) will have an 8 week follow up period i.e. the run in group will not provide mature data and we expect the focus will be on safety rather than efficacy.

Experience from the previous study

The key efficacy measures from the 17 patient study (conducted by Ross et al) from a decade ago were as follows:

- Disease control rate (stable disease or better) 82%;
- Average pain reduction of 35%;
- Median progression free survival of 121 days – note, well outside of the 8 week follow up for the 20 patient run in; and
- Median overall survival of 309 days (10 months) as compared to 8.5 months with the combination of gemcitabine and abraxane and 5.7 months with gemcitabine alone.

In regard to safety, the most frequent grade 3 side effect was Neutropenia (low levels of neutrophils in the blood stream) which occurred in 23% of patients. These patients are more susceptible to bacterial infection.

Neutropenia is a common side effect of many chemotherapies. In OncoPac 1 OncoSil therapy is given in combination with Gemcitabine (as was the case in Ross) hence the Neutropenia is not necessarily due to the OncoSil therapy. In fact, the investigators in the Ross study concluded there were no clinically significant adverse events related to the P^{32} brachytherapy.

We suspect the investigators are primarily concerned with leaching of the radioactive substance out of the pancreas. There was no evidence of this in the Ross study and we suspect the advances made in ultrasound guided endoscopic dosing over the last decade will further reduce this risk.

Likely Timing of Revenues

Following submission of the supplemental data, we expect the CE Mark should be granted in the December quarter of 2017. Patients for the 300 patient clinical trial will be a priority, however, we expect there will be a large patient group not eligible for the trial that may also benefit from OncoSil therapy. The company intends to commence marketing of commercial sales to these patients and to clinics across the EU and in the UK.

There are five large NHS Trusts now participating in Onco Pac 1. In addition we expect prominent hospitals in Western Europe to join. These hospitals should provide a steady

flow of patients not only for the trial, but also commercial sales. The funding arrangements for commercial sales will vary from region to region.

Inclusion/Exclusion Criteria Not Yet Published

OncoSil has not yet published the inclusion and exclusion criteria for OncoPac 1, however, it is reasonable to assume patients with metastatic disease will be excluded. At diagnosis approximately 15% of patients are eligible for surgery, a further 45% have metastatic disease, leaving approximately 40% of patients as inoperable with no metastases.

Similarly, patients with severely impaired wellness (ECOG score > 2) are also likely to be excluded as their life expectancy is significantly less than the expected median overall survival period.

Borderline patients for surgical resection are another category who may benefit.

Some of these patients may show a benefit from OncoSil therapy, particularly the borderline surgical cases. We theorise that if these tumours can be reduced in size, the patient may become a surgical candidate with a potential for cure.

The following lists the hospital groups named so far for participation in the study.

Figure 1 - Onco Pac 1 - participating hospitals

United States	United Kingdom	Australia
MD Andersen Cancer Centre, Texas	Guy's and St Thomas London	Monash Health Cancer Centre
Johns Hopkins, Maryland	University of Leicester	St Vincents, Sydney
The Moffitt Cancer Centre, Florida	Hammersmith Hospital, London	Westmead Hospital, Sydney
Northwestern Memorial, Chicago	Addenbrookes Hospital, Cambridge	RNS Hospital, Sydney
Cedars Sinai Hospital, Los Angles	Royal Liverpool	Royal Adelaide

SOURCE: COMPANY DATA

Four of the five US hospitals are ranked in the top 20 cancer treatment centres in the United States (Cedars Sinai sits just outside this group).

We expect more than 30 centres to be enrolling patients once momentum builds. OncoPac 1 is set enrol 300 patients in total, hence there is plenty of scope for multiple centres to participate. Enrolment is expected to take 2 years.

Valuation and Recommendation

For the 6 months ended 31 December 2016, the net cash burn was $1.7m, while cash reserves were $10.7m at the end of the period.

The cash burn will step up significantly once enrolment of the trial commences with each patient expected to cost US$85K. The forecast assumes the company raises further capital from shareholders during course of the study. OSL has ample funds to complete the 20 patient run in. Commercial sales will also form an important part of the future funding for the trial and these are due to commence shortly.

Figure 2 - Summary of earnings changes

	2017			2018			2019		
	New	Old	% change	New	Old	% change	New	Old	% change
Revenues	3.5	3.5	0%	4.2	5.1	-18%	46.3	47.9	-3%
EBITDA	-7.7	-7.7	0%	-10.8	-10.5	-3%	29.4	30.6	-4%
NPAT	-7.2	-7.2	0%	-10.3	-10.0	-3%	29.9	31.1	-4%
EPS	-1.5	-1.5	0%	-2.0	-1.9	-6%	5.8	6.1	-5%

SOURCE: BELL POTTER SECURITIES

Revenue in FY17 is represented by the R&D tax credit from the Australian Government. Overall changes to earnings are not material.

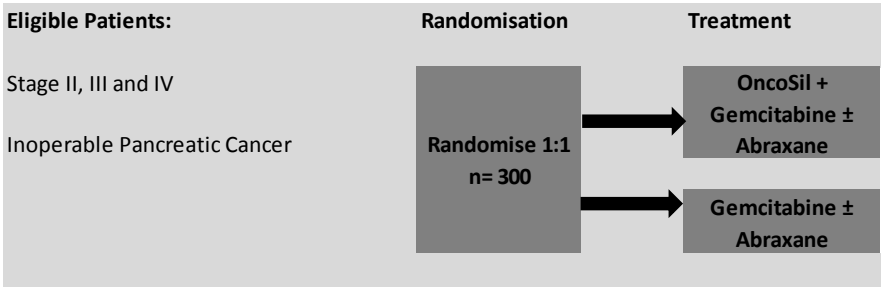
OncoSil Limited

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 85,000 new 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.

OncoPac 1 is an open label, multicentre, international pivotal study investigating the use of OncoSil for the treatment of advanced pancreatic cancer. The US FDA granted an Investigational Device Exemption (IDE) in August 2016.

Figure 3 - Key points from OncoPac-1 trial design



Primary endpoint:	Localised Progression Free Survival
Secondary endpoints:	Overall Survival Progression Free Survival Safety and efficacy Quality of life
Participating countries :	US, Australia, UK, Europe Patients followed until death or 52 week overall survival

SOURCE: COMPANY DATA

The trial will include a 20 patient lead in group (all receiving gemcitabine and OncoSil therapy) mainly to study patient safety. The lead in group will have an 8 week follow up period and the company intends to update the market on these outcomes.

We estimate cost per patient at ~US$85,000, hence the cost of this trial is estimated at between US$24m – US$26m.

OncoSil is a localised therapy being combined with two chemotherapy agents (systemic agents). Median PFS (i.e. progress of the disease either within the pancreas or at any other site) is currently 121 days (based on the earlier pilot study).

Overall survival remains the benchmark for FDA approval, however in this case the FDA has agreed to the primary endpoint of localised progression free survival (LPFS) presumably because patients with advanced pancreatic cancer face such bleak prospects with long term survival rates very low. Controlling the growth of the primary tumour(s) is the priority.

Tumour down staging is also considered an equally important clinical outcome by Oncologists as there is a correlation between down staging and LPFS.

Pain management is also a worthy secondary objective. The earlier clinical trials of OncoSil demonstrated that reductions in pancreatic tumour burden were associated with

meaningful reductions in pain levels. This measure is likely to contribute to quality of life considerations.

Regulatory Pathway

The company has been careful not to discuss an approval pathway that may be associated with outcomes from this trial. OSL previously disclosed that its application for the IDE was accompanied by a premarket approval (PMA). The first step to gaining the PMA is the clinical evidence from a randomised trial. Clinically significant results from OncoPac-1 may lead to marketing approval in the US without the need for a further study. We expect the company will have more to say about its regulatory pathway as results emerge from this study over the next couple of years.

There is no discussion at this time regarding whether the trial is powered for statistical significance or the expected extension in survival rates.

Competing Studies

As there is a large unmet clinical need in pancreatic cancer, we would expect other clinical trials will run in conjunction with OncoPac-1. The register of these trials is available at clinicaltrials.gov.

A search of this site reveals a number of studies in early stages (Phase I or IIb) and generally each of these is combination of a checkpoint inhibitor with a chemotherapy and or radiation therapy.

Based on our experience from following clinical trials in various cancers, it is unlikely (but not impossible) that any one combination will emerge that will materially extend survival rates in advanced pancreatic cancer. Checkpoint inhibitors (including Keytruda) are not approved in treatment of pancreatic cancer. Merck does not appear to be focussing on this disease in its extensive clinical trial program.

We note that MD Anderson is also a collaborator in some of these studies. As this hospital is a leading cancer treatment centre, its involvement in various clinical trials is to be expected. MD Anderson is likely to receive dozens of approaches each year for participation in various clinical studies. The fact that it has agreed to participate in OncoPac-1 is a testimony to the validity of OncoSil microspheres.

Our view at this time remains, that should OncoSil deliver clinical outcomes that replicate the efficacy seen in earlier trials (as discussed elsewhere in this report) then it is likely the therapy will have a prominent position in the treatment landscape for pancreatic cancer.

Key Risk Areas

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. While the company is confident, that fact is that Oncosil has not been trialled in combination with the current standard of care (Abraxane and Gemcitabine). While the likely risk of rejection is minimal, it remains a risk.

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 require further equity in order to complete OncoPac-1.

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 Ltd
as at 28 March 2017

Recommendation	Buy, Speculative
Price	$0.08
Valuation	$0.39

Table 1 - Financial summary

Profit & Loss (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Year Ending June					
Dose sales (units)	-	-	-	120	450
Net revenue from product sales	-	-	-	0.7	3.3
COGS	-	-	-	-0.3	-0.7
Gross profit	-	-	-	0.4	2.6
GP margin	0%	50%	50%	60%	80%
R&D incentive/Upfront receipts	2.8	3.8	3.5	3.5	43.0
Total revenues	**2.8**	**3.8**	**3.5**	**4.2**	**46.3**
Other expenses	**-5.7**	**-8.8**	**-11.2**	**-14.8**	**-16.2**
EBITDA	**-2.9**	**-5.0**	**-7.7**	**-10.8**	**29.4**
Depreciation	0.0	0.0	0.0	0.0	0.0
Amortisation	0.0	0.0	0.0	0.0	0.0
EBIT	-2.9	-5.0	-7.7	-10.8	29.4
Sundry income	0.0	0.3	0.5	0.5	0.5
Pre tax profit	-2.9	-4.8	-7.2	-10.3	29.9
Tax expense	-	-	-	-	-
NPAT- normalised	-2.9	-4.8	-7.2	-10.3	29.9
Net abnormal items	-	-	-	-	-
Reported NPAT	-2.9	-4.8	-7.2	-10.3	29.9

Cashflow (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Gross cashflow	-0.3	-6.4	-5.1	-11.0	29.0
Net interest	0.3	0.3	0.5	0.5	0.6
Tax paid	0.0	0.0	0.0	0.0	0.0
Operating cash flow	-0.1	-4.6	-4.6	-10.5	29.6
Maintenance capex	0.0	-0.1	0.0	0.0	0.0
Capitalised clinical trial spend	0.0	0.0	-1.7	-9.0	-20.0
Free cash flow	-0.1	-4.6	-6.4	-19.5	9.6
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	0.0	11.9	0.0	17.0	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	(0.1)	7.3	(6.4)	(2.5)	9.6
Cash at beginning of period	2.6	2.5	9.8	3.4	1.0
Cash at year end	2.5	9.8	3.4	1.0	10.5

Balance Sheet (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Cash	2.5	9.8	3.4	1.0	10.5
Receivables	0.1	2.6	-	0.1	0.6
Short term investments	3.6	3.3	3.3	3.3	3.3
Other current assets	1.2	0.1	0.1	0.1	0.1
Property, Plant and Equipment	0.1	0.1	0.1	0.1	0.1
Intangible assets	-	-	1.7	10.7	30.7
Total assets	7.4	15.9	8.7	15.4	45.3
Trade payables	0.4	1.0	1.0	1.0	1.0
Other provisions	0.1	0.1	0.1	0.1	0.1
Total Liabilities	0.4	1.1	1.1	1.1	1.1
Net Assets	7.0	14.8	7.6	14.3	44.2
Share capital	23.8	35.7	35.7	52.7	52.7
Retained earnings	(18.7)	(23.5)	(30.7)	(41.0)	(11.1)
Reserves	1.9	2.6	2.6	2.6	2.6
Shareholders Equity	7.0	14.8	7.6	14.3	44.2

Valuation Ratios (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Reported EPS (cps)	-0.8	-1.2	-1.5	-2.0	5.8
Normalised EPS (cps)	-0.8	-1.2	-1.5	-2.0	5.8
EPS growth (%)	-43%	-46%	-28%	-34%	nm
PE(x)	**nm**	**nm**	**nm**	**nm**	**nm**
EV/EBITDA (x)	-9.1	-5.2	-3.4	-2.4	0.9
EV/EBIT (x)	-9.1	-5.3	-3.4	-2.4	0.9
NTA (cps)	2.0	3.2	1.3	0.7	2.6
P/NTA (x)	0.0	0.0	0.1	0.1	0.0
Book Value (cps)	2.0	3.2	1.6	2.8	8.6
Price/Book (x)	0.0	0.0	0.0	0.0	0.0
DPS (cps)	-	-	-	-	-
Payout ratio %	0%	0%	0%	0%	0%
Dividend Yield %	0.0%	0.0%	0.0%	0.0%	0.0%
Franking %	0%	0%	0%	0%	0%
FCF yield %	nm	nm	nm	nm	nm
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)	FY17e	FY18e	FY19e
Europe	-	100	350
USA	-	-	-
Australia/Asia Pacific	-	20	100
Total dose sales	**-**	**120**	**450**

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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