BELL POTTER

9 November 2016

Speculative

Refer to key risks on page 4 and Biotechnology Risk Warning on page 7. Speculative securities may not be suitable for retail clients.

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Oncosil (OSL)

OncoPac-1 Commencing Recruitment in 1QCY17

Recommendation
Buy (unchanged)
Price
$0.105
Valuation
$0.39 (previously $0.33)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

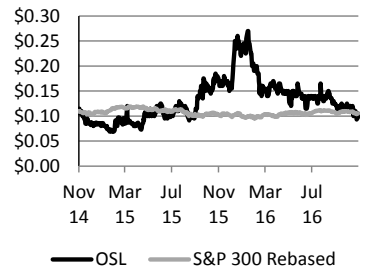
Expected Return	
Capital growth	**271%**
Dividend yield	**0%**
Total expected return	**271%**

Company Data & Ratios	
Enterprise value	**$36.2m**
Market cap	**$49.2m**
Issued capital	**468.5m**
Free float	**100%**
Avg. daily val. (52wk)	**$287,000**
12 month price range	**$0.09 - $0.28**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.12	0.15	0.18
Absolute (%)	-12.50	-30.00	-40.00
Rel market (%)	-8.92	-26.17	-40.53

Absolute Price



SOURCE: IRESS

Highlights From Quarterly Update

The company conducted its regular quarterly update this week. Key points were:

The OncoPac-1 study is set to commence recruitment in 1QCY17 at 10 prestigious oncology centres around the world, headlined by MD Anderson (Texas) and Johns Hopkins (Baltimore). These two hospitals are ranked #1 and #9 respectively in the treatment of adult cancers in the US. The involvement of these two institutions comes as no surprise given the breakthrough nature of the study and the absence of any recent innovation in the treatment for advanced pancreatic cancer. Other hospital in active preparation (i.e. working through ethics approval) include five NHS hospitals in the UK and three in Australia. The first 20 patients in the "run in" are expected to commence recruitment in early calendar 2017 and report in the second half of the year – we expect as soon as July or August 2016.

In Europe, OSL has now closed out all remaining points with the British Standards Institute following a meeting with this body earlier in November. The BSI is responsible for recommending CE Mark Approval which will be an important step towards progressing the first commercial sale which we now expect will occur in calendar 2017.

OSL had $13.8m in cash as at 30 September 2016 which is more than sufficient to complete the first 20 patients in OncoPac-1. The cash burn through to 30 June 2017 is expected to run at approximately $2m/qtr including the cost of the clinical trial.

Retain Buy Recommendation

The next 8 months will be a frenetic period. Even though the OncoPac-1 trial is about to commence, the risks remain high as this is a first in class device, never previously administered in the US. The FDA and the hospitals involved will be watching carefully. We remind investors that earlier trials of this therapy achieved a stunning 82% disease control rate. The CEO and his team have progressed this therapy an extraordinary distance in the last 18 months and the company is now at the cusp of being into the clinic. We retain the Buy rating. Valuation is raised to $0.39 (from $0.33).

Earnings Forecast

June Year End	FY16	FY17e	FY18e	FY19e
Revenues	3.8	3.5	5.1	47.9
EBITDA $m	-5.0	-7.7	-10.5	30.6
NPAT (underlying) $m	-4.8	-7.2	-10.0	31.1
NPAT (reported) $m	-4.8	-7.2	-10.0	31.1
EPS underlying (cps)	-1.2	-1.5	-1.9	6.1
EPS growth %	-46%	-27%	-31%	nm
PER (x)	nm	nm	nm	nm
FCF yield (%)	nm	nm	nm	nm
EV/EBITDA (x)	-7.2	-4.7	-3.4	1.2
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	-33.8%	-100.5%	-71.8%	66.9%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Patient Safety Is Key

The 20 patient run in will be examined by the FDA as part of the ongoing trial process. We expect the primary focus will be patient safety and specifically examining any evidence that diluent leaked outside of the pancreas, and if so why did it occur and what were the impacts. This is a key area as there is significant potential for serious injury to patients.

The issue of leakage has been extensively addressed in submissions to the FDA and BSI. The company believes the risk of leakage is minimal.

Oncosil was trialled in 17 late stage patients in approximately 2006/07.

Result summary:

Safety:

- Safety – no serious adverse events reported in relation to the P^{32}. A small percentage of patients suffered grade 3 serious adverse events typically associated with the chemotherapy. These included nausea & vomiting (1), abdominal pain (1) and neutropenia (2).
- No significant systemic leakage of P^{32} from the implantation.

Efficacy

- Disease control rate of 82%.
- 4 partial responses, 10 stable disease and 3 patients progressed. 50% of patients experienced at least a 30% reduction in tumour size.
- Patients experienced an average pain reduction of 35% with a maximum reduction of 69% between weeks 8 and 11 following implant.
- Median progression free survival was 121 days.
- Median overall survival was 309 days (10 months) as compared to 8.5 months with the combination of gemcitabine and abraxane and 5.7 months with gemcitabine alone.

The company is quietly confident that it can at least meet these performance benchmarks. This confidence stems from the following:

- Top tier hospitals will be participating in the trial. The best gastroenterologists practice in these facilities assisted by the best of the multidisciplinary teams.
- Imaging technology has progressed monumentally in the last decade since the pilot study. 3D CT imaging machines and specialised ultrasound are now used to guide the surgeon allowing precision placement of the radioactive load of therapy to the hot area of the tumour. This technology was not previously available. Logic says that this should improve patient outcomes, albeit we await the clinical trial results.
- In order to validate the manufacturing and distribution processes, the company recently performed a full hot calibration run of OncoSil microparticles. This was performed at the Department of Nuclear Medicine, Royal North Shore (RNS) Hospital, Sydney. We expect further live training runs in Europe and the US prior to treatment of the first patients.

CE MARK

The CE Mark process is moving forward with the CEO and CMO from Oncosil attending a meeting with the BSI in London earlier this month. Based on the commentary from the investor call, we understand this meeting went well and all outstanding issues have now

been closed out. It remains to be seen whether the approval body will require further data from the company.

We continue to anticipate a small number of sales in Europe in FY17 which are contingent upon the CE Mark being received, however, the company's focus will be on OncoPac-1 in 2017 as opposed to driving revenue growth in Europe.

NEXT CATALYSTS

- Announcement of further hospitals participating in the clinical trial.
- First patient enrolment on OncPac-1 expected 1QCY17.
- CE Mark Approval – timing uncertain.
- Reporting of first 20 patients from the clinical trial.

Figure 1 - Summary of Earnings Changes

	2017			2018			2019		
	New	Old	% change	New	Old	% change	New	Old	% change
Revenues	3.5	3.5	0%	5.1	5.1	1%	47.9	50.2	-5%
EBITDA	-7.7	-6.1	-21%	-10.5	-10.5	0%	30.6	31.5	3%
NPAT	-7.2	-5.6	-22%	-10.0	-10.0	0%	31.1	32.0	3%
EPS	-1.5	-1.2	-19%	-1.9	-1.9	-3%	6.1	6.2	2%

SOURCE: BELL POTTER SECURITIES ESTIMATES

In FY17 we have amended operating costs in the model to reflect the run rate from FY16. There are no significant changes to earnings in later years of the forecast.

The model assumes OSL will capitalise at a portion of the clinical trial costs from FY17 and beyond.

Our valuation continues to be based upon a risk adjusted discounted cash flow model. If the first 20 patients in the OnoPac-1 study are treated successfully – i.e. with no serious adverse safety events, this may provide cause to change the risk assumptions in the model.

As the company is now on the verge of commencing what is likely to be an approval study, we consider that the market cap of $49m represents deep value, albeit OSL will retain a speculative rating during the course of the trial period.

Valuation is raised from $0.33 to $0.39 following a roll forward of the model.

Key Risk Areas

CE Mark – timing of the receipt of the CE Mark remains uncertain. 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 required 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.

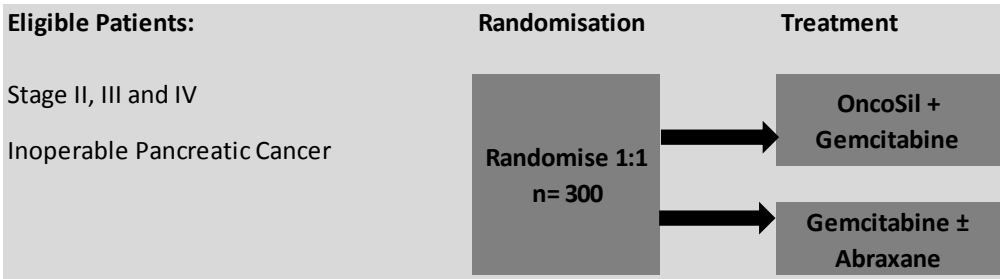
OncoSil Limited

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.

OncoPac-1 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.

Figure 2 - 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: BELL POTTER SECURITIES

The trial will include a 20 patient lead in group (all receiving the 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 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.

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 clinical trials.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.

Oncosil
as at 9 November 2016

Recommendation	Buy, Speculative
Price	$0.105
Valuation	$0.39

Table 1 - Financial summary

Profit & Loss (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Year Ending June					
Dose sales (units)	-	-	70	140	660
Net revenue from product sales	-	-	0.5	2.1	4.9
COGS	-	-	- 0.3	-0.9	-1.0
Gross profit	-	-	0.3	1.3	3.9
GP margin	0%	50%	50%	60%	80%
R&D incentive/Upfront receipts	2.8	3.8	3.0	3.0	43.0
Total revenues	**2.8**	**3.8**	**3.5**	**5.1**	**47.9**
Other expenses	**-5.7**	**-8.8**	**-10.9**	**-14.8**	**-16.3**
EBITDA	**-2.9**	**-5.0**	**-7.7**	**-10.5**	**30.6**
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	-10.5	30.6
Sundry income	0.0	0.3	0.5	0.5	0.5
Pre tax profit	-2.9	-4.8	-7.2	-10.0	31.1
Tax expense	-	-	-	-	-
NPAT- normalised	-2.9	-4.8	-7.2	-10.0	31.1
Net abnormal items	-	-	-	-	-
Reported NPAT	-2.9	-4.8	-7.2	-10.0	31.1

Cashflow (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Gross cashflow	-0.3	-6.4	-5.1	-10.8	30.1
Net interest	0.3	0.3	0.5	0.5	0.5
Tax paid	0.0	0.0	0.0	0.0	0.0
Operating cash flow	-0.1	-4.6	-4.6	-10.3	30.6
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	-19.4	10.6
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)	(2.3)	10.6
Cash at beginning of period	2.6	2.5	9.8	3.5	1.1
Cash at year end	2.5	9.8	3.5	1.1	11.8

Balance Sheet (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Cash	2.5	9.8	3.4	1.1	11.7
Receivables	0.1	2.6	0.1	0.4	0.8
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	0.2	0.2
Intangible assets	-	-	1.7	10.7	30.7
Total assets	7.4	15.9	8.7	15.7	46.9
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	14.7	45.8
Share capital	23.8	35.7	35.7	52.7	52.7
Retained earnings	(18.7)	(23.5)	(30.7)	(40.7)	(9.6)
Reserves	1.9	2.6	2.6	2.6	2.6
Shareholders Equity	7.0	14.8	7.6	14.7	45.8

Last sale 08/11/2016	0.105
Recommendation	Buy (Spec)
Issued Capital	468.5
Market Cap	49.2

Valuation Ratios (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Reported EPS (cps)	-0.8	-1.2	-1.5	-1.9	6.1
Normalised EPS (cps)	-0.8	-1.2	-1.5	-1.9	6.1
EPS growth (%)	-43%	-46%	-27%	-31%	nm
PE(x)	**nm**	**nm**	**nm**	**nm**	**nm**
EV/EBITDA (x)	-12.5	-7.2	-4.7	-3.4	1.2
EV/EBIT (x)	-12.5	-7.2	-4.7	-3.4	1.2
NTA (cps)	2.0	3.2	1.3	0.8	2.9
P/NTA (x)	0.1	0.0	0.1	0.1	0.0
Book Value (cps)	2.0	3.2	1.6	2.9	8.9
Price/Book (x)	0.1	0.0	0.1	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 %	108%	0%	0%	0%	0%
FCF yield %	-32%	-1265%	-961%	-1915%	5671%
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	50	100	560
USA	-	-	-
Australia/Asia Pacific	20	40	100
Total dose sales	**70**	**140**	**660**

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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