BELL POTTER

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Speculative

See key risks on Page 3 and Biotechnology Risk Warning on Page 7. Speculative securities may not be suitable for Retail Clients.

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Oncosil (OSL)

First Glimpse At Efficacy Data from Onco Pac 1

Recommendation
Buy (unchanged)
Price
$0.155
Valuation (12 months)
$0.41 (unchanged)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

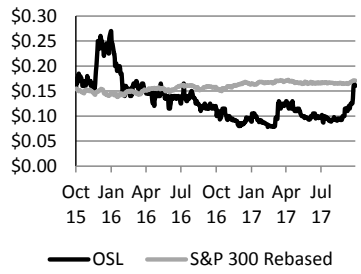
Expected Return	
Capital growth	**165%**
Dividend yield	**0.0%**
Total expected return	**165%**

Company Data & Ratios	
Enterprise value	**$67.6m**
Market cap	**$75.6m**
Issued capital	**487m**
Free float	**100%**
Avg. daily val. (52wk)	**$74,000**
12 month price range	**$0.076 - $0.18**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.10	0.10	0.12
Absolute (%)	68.42	60.00	33.33
Rel market (%)	65.24	56.28	24.55

Absolute Price



SOURCE: IRESS

100% Disease Control Rate

Pancreatic cancer has been one of many graveyards for oncology drug developers over a period of decades, indeed the pathway to success in the clinic has been a challenging one for Oncosil over the last 18 months. Nevertheless the first efficacy data from Onco Pac 1 has emerged and it appears the wait has been worthwhile.

All patients in the trial have inoperable localised pancreatic cancer (no metastatic spread). The primary endpoint is local progression free survival with overall survival as a secondary endpoint in this 300 patient pivotal study. The Oncosil device is being trialled in combination with gemcitabine ± abraxane.

The data trends from the first twelve patients, all of whom received the chemotherapy plus Oncosil, shows a disease control rate of 100% meaning that all patients experienced stable disease or better. The median tumour volume reduction was 34.5% with one patient experiencing a 73% reduction at 4 weeks post implantation. The company did not provide further analysis regarding other partial responses, however it is clear that a number of patients experienced significant reduction in tumour volume and this would be consistent with the prior monotherapy study.

The safety data is also highly encouraging. There was no evidence of radiation toxicity or serious adverse event associated with the device. Side effects were of the normal profile associated with the use of chemotherapy.

The trial has now recruited a total of 28 patients. While the recruitment rates are slower than the company would like, the pace of recruitment is improving. These results should further accelerate recruitment and we are now hopeful that 10 new patients per month is realistic.

Maintain Buy (Speculative) Rating

There are no significant changes to our earnings forecasts. We retain our Buy (speculative) rating and valuation of $0.41.

Earnings Forecast

June Year End	FY17	FY18e	FY19e	FY20e
Revenues	3.4	3.5	44.8	9.6
EBITDA $m	-7.3	-13.2	26.5	-10.1
NPAT (underlying) $m	-7.0	-12.7	27.0	-9.6
NPAT (reported) $m	-7.0	-12.7	27.0	-9.6
EPS underlying (cps)	-1.5	-2.3	4.9	-1.8
EPS growth %	-28%	-55%	nm	-136%
PER (x)	nm	nm	nm	nm
FCF yield (%)	nm	nm	nm	nm
EV/EBITDA (x)	-9.2	-5.1	2.6	-6.7
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	-71.9%	-75.0%	59.5%	-29.0%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Oncosil Therapy Safe To Use With Chemo

Oncosil has provided the first glimpse of efficacy data from its clinical trial in the use of the Oncosil device for the treatment of inoperable Pancreatic Cancer.

The following results were presented at The European Association of Nuclear Medicine Congress held in Vienna over the weekend. The highlights were:

- 12 subjects had reached the first evaluation point at week 8 (being 4 weeks post implantation with Oncosil therapy);
- Patients demonstrated median volumetric reduction in tumours of 34.5%, including one patient that showed a 73% reduction in tumour volume;
- 100% of patients showed response to therapy; and
- No evidence of radiation toxicity. No serious adverse events related to the device or the implant procedure.

Detailed results from individual patients have not been made available, however we understand there were some significant data trends emerging in tumour volume reduction. While it is too early to speak of progress against clinical endpoints, at the very least there are encouraging signs.

SYNERGY BENEFITS WITH CHEMOTHERAPY?

The Oncosil device had not previously been used in combination with Gemcitabine ± Abraxane (being the standard of care for pancreatic cancer). A key comparison, therefore, is the presence or absence of synergy benefits with the chemotherapy. These details are yet to emerge, however, the fact that we are seeing a 100% DCR is strongly suggestive of a synergy benefit.

In the view of the company, the results demonstrate excellent local disease control and provide evidence of the down staging potential of the Oncosil device.

We consider this comment about down staging is highly relevant. It indicates the company is likely to pursue borderline cases for resection in the hope that tumours can be reduced in volume, potentially to a size where surgery is viable. This may expand the potential population which may benefit from the Oncosil device.

NEXT STEPS

The next step for Oncosil is to complete the data package for the first 20 patients ahead of a likely CE Mark approval in early 2018. While patient recruitment has been frustratingly slow due to delays in the UK and the US, we now expect the submission of the data package on the first 20 patients shortly before year end. If the 34% median reduction in tumour volume is sustained, along with the safety profile, the CE Mark approval looks to be significantly de-risked.

The next update on efficacy is also likely before calendar year end. The content will most likely depend on the strength of the data at each evaluation point (being weeks 8, 16 & 24). At the very least we believe the data released over the weekend should be a significant catalyst for patient recruitment in Europe.

The primary endpoint of the trial is localised progression free survival (LPSF). A Secondary endpoint is overall survival where patients are followed until death of a minimum 12 months.

In our view it is not unreasonable to link these encouraging signs on safety, disease control rates and tumour volume reduction to a likelihood of a statistical improvement in LPFS. It is too early to discuss an overall survival benefit at this point.

Figure 1 - Summary of earnings changes

	2018			2019		
	New	Old	% change	New	Old	% change
Revenues	3.5	5.0	-30%	44.8	46.3	-3%
EBITDA	-13.2	-10.6	-20%	26.5	29.4	-10%
NPAT	-12.7	-10.1	-20%	27.0	29.9	-10%
EPS	-2.3	-1.9	-18%	4.9	5.6	-12%

SOURCE: BELL POTTER SECURITIES

We have processed minor revenues changes resulting in changes to NPAT. While these adjustments to earnings are large in percentage terms, the dollar value of the earnings changes are considered immaterial.

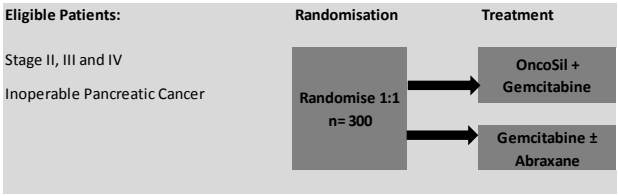
OncoSil Limited

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

Patient receive up to three doses of the chemotherapy regime one week apart, followed by implantation of the Oncosil device via ultrasound guided endoscopy in the 4th week. Thereafter patients continue on the chemotherapy.

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.

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 OncoPac-1. 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
as at 23 October 2017

Recommendation	Buy, Speculative
Price	$0.155
Valuation (12 months)	$0.41

Table 1 - Financial summary

Profit & Loss (A$m)	FY16	FY17	FY18e	FY19e	FY20e
Year Ending June					
Dose sales (units)	-	-	70	250	1,190
Net revenue from product sales	-	-	0.5	1.8	6.6
COGS	-	-	- 0.2	-0.4	-1.3
Gross profit	-	-	0.3	1.5	5.3
GP margin	50%	50%	60%	80%	80%
R&D incentive/Upfront receipts	3.8	3.4	3.0	43.0	3.0
Total revenues	**3.8**	**3.4**	**3.5**	**44.8**	**9.6**
Other expenses	**-8.8**	**-10.8**	**-16.5**	**-18.0**	**-18.4**
EBITDA	**-5.0**	**-7.3**	**-13.2**	**26.5**	**-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	-5.0	-7.3	-13.2	26.5	-10.1
Sundry income	0.3	0.3	0.5	0.5	0.5
Pre tax profit	-4.8	-7.0	-12.7	27.0	-9.6
Tax expense	-	-	-	-	-
NPAT- normalised	-4.8	-7.0	-12.7	27.0	-9.6
Net abnormal items	-	-	-	-	-
Reported NPAT	-4.8	-7.0	-12.7	27.0	-9.6

Cashflow (A$m)	FY16	FY17	FY18e	FY19e	FY20e
Gross cashflow	-6.4	-8.6	-12.7	26.5	-10.1
Net interest	0.3	0.2	0.6	0.6	0.5
Tax paid	0.0	0.0	0.0	0.0	0.0
Operating cash flow	-4.6	-6.1	-12.1	27.1	-9.6
Maintenance capex	-0.1	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	-4.6	-6.2	-12.2	27.0	-9.7
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	11.9	1.0	20.0	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	7.3	(5.2)	7.9	27.0	(9.7)
Cash at beginning of period	2.5	9.8	8.0	15.9	42.9
Cash at year end	9.8	8.0	15.9	42.9	33.2

Balance Sheet (A$m)	FY16	FY17	FY18e	FY19e	FY20e
Cash	9.8	8.0	15.9	42.9	33.2
Receivables	2.6	3.5	3.0	3.0	3.0
Short term investments	3.3	-	-	-	-
Other current assets	0.1	0.2	0.1	0.1	0.1
Property, Plant and Equipment	0.1	0.1	0.2	0.2	0.2
Intangible assets	-	-	-	-	-
Total assets	15.9	11.9	19.2	46.2	36.6
Trade payables	1.0	1.5	1.5	1.5	1.5
Other provisions	0.1	0.1	0.2	0.2	0.2
Total Liabilities	1.1	1.7	1.7	1.7	1.7
Net Assets	14.8	10.2	17.6	44.5	34.9
Share capital	35.7	36.7	56.7	56.7	56.7
Retained earnings	(23.5)	(30.5)	(43.2)	(16.2)	(25.8)
Reserves	2.6	4.0	4.0	4.0	4.0
Shareholders Equity	14.8	10.2	17.6	44.5	34.9

Last sale 23/10/2017	0.155
Recommendation	Buy (Spec)
Issued Capital	487.5
Market Cap	75.6

Valuation Ratios (A$m)	FY16	FY17	FY18e	FY19e	FY20e
Reported EPS (cps)	-1.2	-1.5	-2.3	4.9	-1.8
Normalised EPS (cps)	-1.2	-1.5	-2.3	4.9	-1.8
EPS growth (%)	-46%	-28%	-55%	nm	-1.4
PE(x)	**nm**	**nm**	**nm**	**nm**	**nm**
EV/EBITDA (x)	-13.5	-9.2	-5.1	2.6	-6.7
EV/EBIT (x)	-13.5	-9.2	-5.1	2.6	-6.7
NTA (cps)	3.2	2.1	3.2	8.1	6.4
P/NTA (x)	0.0	0.1	0.0	0.0	0.0
Book Value (cps)	3.2	2.1	3.2	8.1	6.4
Price/Book (x)	0.0	0.1	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 %	140%	0%	0%	0%	0%
FCF yield %	-857%	-1119%	-1435%	3184%	-1140%
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)	FY18e	FY19e	FY20e
Europe	50	150	1,050
USA	-	-	-
Australia/Asia Pacific	20	100	140
Total dose sales	**70**	**250**	**1,190**

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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