BELL POTTER

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Speculative

See key risks on Page 4 and Biotechnology Risk Warning on Page 6. Speculative securities may not be suitable for Retail Clients.

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Oncosil (OSL)

US Program Accelerates

Recommendation
Buy (unchanged)
Price
$0.12
Valuation (12 months)
$0.38 (previously $0.30)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

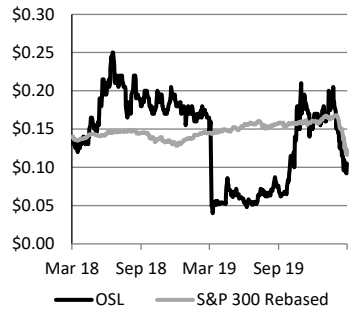
Expected Return	
Capital growth	**217%**
Dividend yield	**0.0%**
Total expected return	**217%**

Company Data & Ratios	
Enterprise value	**$68.7m**
Market cap	**$75.7m**
Issued capital	**630.7m**
Free float	**100%**
Avg. daily val. (52wk)	**$300,000**
12 month price range	**$0.02 - $0.22**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.19	0.16	0.17
Absolute (%)	-43.2	-34.4	-36.4
Rel market (%)	-12.8	-8.1	-16.5

Absolute Price



SOURCE: IRESS

Breakthrough Designation Reduces Risk Profile

The FDA has granted Oncosil breakthrough device designation for the treatment of unresectable, locally advanced pancreatic cancer in combination with systemic chemotherapy. The announcement comes as a welcome surprise and will materially accelerate the path to US revenues.

Breakthrough designation is not common, however, the benefits are significant. The company will have priority access to FDA consultants during the design of the clinical trial as well as expedited meetings (with the FDA) and a range of concession in order to fast track the approval process. Oncosil will still be required to conduct a clinical trial in the US, but there is now potential for an accelerated approval based on a review of interim data. We estimate the trial may require between 100 and 200 participants and commence in CY2021. We understand the breakthrough designation was based on a dossier of largely the same data submitted to the European regulators.

The addressable market in the US is large. There are approximately 48,000 new cases annually of which we estimate ~42% (20,000 patients) are unresectable, locally advanced. The Oncosil device, if approved, will be the first innovation in the treatment of this disease since 2013. Elsewhere the company awaits the CE Mark for Europe. The short term impact of the COVID19 crises has made it impractical to launch the product and therefore we expect a launch will be delated until 2H CY2020.

Retain Buy (Speculative) Valuation Raised to $0.38

In our view the awarding of breakthrough designation together with the clinical data from PanCo significantly increases the likelihood of a US approval. For these reasons we have lowered the risk rating attached to future US revenues. Accordingly the valuation which is based on a DCF is increased to $0.38 from $0.30 and we maintain our Buy (Speculative) recommendation. There are modest changes to earnings associated with a delay to the product launch in Europe and incorporation of expected clinical trial costs.

Earnings Forecast

June Year End	FY19	FY20e	FY21e	FY22e
Revenues	3.6	3.6	6.7	11.8
EBITDA $m	-8.7	-7.9	-16.5	-14.8
NPAT (underlying) $m	-8.5	-7.7	-16.4	-14.7
NPAT (reported) $m	-8.5	-7.7	-16.4	-14.7
EPS underlying (cps)	-1.4	-1.2	-2.0	-1.8
EPS growth %	nm	-9%	61%	-11%
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 %	-81.6%	-266.0%	-45.3%	-67.6%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Breakthrough Designation

OSL has announced that the FDA has granted Oncosil breakthrough device designation for the treatment of unresectable, locally advanced pancreatic cancer in combination with systemic chemotherapy.

The granting of this designation is infrequent for new drugs and devices. In 2019, 26 drugs were given Breakthrough Designation and of these 12 were supplements for new indications of already approved drugs. Of the 14 new drugs, nine were for oncology indications. The data for devices is not available.

Oncosil's regulatory body within the FDA is the Center for Device and Radioloical Health (rather than the larger and more widely known CDER which handles all new and generic drug registrations). All the advantages for breakthrough designation via the more familiar CDER also apply for devices. The key requirement for breakthrough designation is that the device provides a more effective treatment for a life threatening disease and its use must be in the best interest of patients (i.e. benefits outweigh the risks).

The announcement comes as somewhat of a surprise as previous statements from the company had concentrated on entry to the US market via a humanitarian device exemption for bile duct cancer.

The breakthrough designation is significant for the several reasons:

The FDA has now clearly conducted a detailed review of the data from Oncosil's clinical trial for the treatment of unresectable pancreatic cancer conducted in the UK and Australia (the PanCo study). Between this trial and the special access scheme in Australia, there are dozens of patients that have now received the therapy.

The key data from PanCo was presented at ASCO in June 2019. The highlights were:

- Interim median survival of 16 months in the per protocol group vs approximately 11 months in the standard of care;
- 1 year survival of 64% vs 50% on SOC; and
- Improved resection rates which lead to potentially curative surgery; and
- There were no serious safety concerns.

OSL will now follow the pre market approval (PMA) pathway in the US for the treatment of pancreatic cancer. No surprise here as Oncosil is a class III medical device which requires data from a randomised trial. The first indication is locally advanced unresectable pancreatic cancer.

The PMA will require most likely one large pivotal study with between 100 to 200 patients. Normally there is a 12 month review period for a PMA.

The major advantage of the Breakthrough designation being that there is potential for an accelerated approval based on an interim review of the data and an interim clinical endpoint (progression free survival is commonly used in oncology). The company alludes to this with the reference to the gathering of some data in the post market setting. Numerous drugs have come to market in recent years on the same basis, most notably Merck's blockbuster pembrolizumab (keytruda).

The other benefits of the breakthrough device program (BDP) are pragmatic. The BDP offers manufacturers an opportunity to interact with the FDA's experts during the design of the clinical trial as well as at every other stage of the program and data submission process. This interaction could potentially expedite the commencement of a clinical program by up to six months. The best case scenario being that OSL may be in a position to start a pivotal study in early CY2021.

Separately, OSL will continue with the Humanitarian Device Exemption program for bile duct cancer.

OSL still awaits the CE Mark for Europe, however, the COVID-19 crisis will inevitably delay the launch in Europe for several months as the company reps won't have access to hospitals for training and accreditation. In the interim OSL now has ample time to concentrate on its now dual pathway for the US while conserving capital in preparation for a product launch Europe later this calendar year. Once the CE Mark is obtained the company will also pursue registrations in Australia, Singapore, Japan and numerous individual markets in Europe.

As at 31 December the company had cash and receivables of ~$8m with a cash burn (before the R&D refund) of $2.5m, hence there is sufficient cash for several months. A large clinical trial is likely to require further equity, however, we have now pushed back the timing of the raise into FY21. Ideally OSL will generate cash from sales in Australia and Europe to assist with the funding of the US study.

Other changes to earnings include a delay in revenues from Europe and we have adjusted the R&D cost for a US clinical trial. The final cost of the trial is yet to be determined. The financial model assumes US$30K per dose in the US commencing from FY24. Both these assumptions are conservative with the potential for an accelerated approval as outlined above.

Figure 1 - summary of earnings changes

	2020			2021			2022		
	New	Old	% change	New	Old	% change	New	Old	% change
Revenues	3.6	3.6	0.0%	6.7	6.5	4%	11.8	11.3	4%
EBITDA	-7.9	-13.6	42.3%	-16.5	-18.7	12%	-14.8	-22.6	35%
NPAT	-7.7	-13.5	42.6%	-16.4	-18.6	12%	-14.7	-22.4	35%
EPS	-1.2	-1.6	22.5%	-2.0	-2.3	13%	-1.8	-2.7	34%

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

In our view the awarding of breakthrough designation together with the clinical data from PanCo significantly increases the liklihood of a US approval. For these reasons we have also lowered the risk rating attached to future US revenues. Accordingly the valuation which is based on a DCF is increased to $0.38 from $0.30 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 the treatment of inoperable, locally advanced 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 and as well as breakthrough designation. 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 pivotal 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 require 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
as at 19 March 2020

Recommendation	Buy, Speculative
Price	$0.12
Target (12 months)	$0.38

Table 1 - Financial summary

Profit & Loss (A$m)	FY18	FY19	FY20e	FY21e	FY22e
Year Ending June					
Dose sales (units)	-	-	-	205	490
Net revenue from product sales	-	-	0.6	3.7	6.8
COGS	-	-	- 0.1	-0.7	-1.4
Gross profit	-	-	0.5	3.0	5.4
GP margin				80%	80%
R&D incentive/Upfront receipts	4.4	3.6	3.0	3.0	5.0
Total revenues	**4.4**	**3.6**	**3.6**	**6.7**	**11.8**
Other expenses	**-5.8**	**-5.6**	**-4.0**	**-10.0**	**-12.0**
Other expenses	**-13.1**	**-6.7**	**-7.3**	**-12.5**	**-13.2**
EBITDA	**-8.7**	**-8.7**	**-7.9**	**-16.5**	**-14.8**
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	-7.8	-16.5	-14.8
Sundry income	0.2	0.2	0.1	0.1	0.1
Pre tax profit	-8.6	-8.5	-7.7	-16.4	-14.7
Tax expense	-	-	-	-	-
NPAT- normalised	-8.6	-8.5	-7.7	-16.4	-14.7
Net abnormal items	-	-	-	-	-
Reported NPAT	-8.6	-8.5	-7.7	-16.4	-14.7

Cashflow (A$m)	FY18	FY19	FY20e	FY21e	FY22e
Gross cashflow	-8.5	-7.7	-7.0	-13.9	-15.3
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	-6.9	-13.8	-15.2
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	-6.9	-13.8	-15.2
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	15.6	0.0	0.0	50.0	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)	(6.9)	36.2	(15.2)
Cash at beginning of period	8.0	15.2	7.7	0.7	36.9
Cash at year end	15.2	7.7	0.7	36.9	21.7

Balance Sheet (A$m)	FY18	FY19	FY20e	FY21e	FY22e
Cash	15.2	7.7	0.7	36.9	21.7
Receivables	4.5	3.8	3.0	0.4	0.9
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	19.9	11.7	4.0	37.5	22.9
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	18.2	10.7	3.0	36.5	21.8
Share capital	52.3	52.3	52.3	102.3	102.3
Retained earnings	(39.1)	(47.6)	(55.3)	(71.8)	(86.4)
Reserves	5.0	6.0	6.0	6.0	6.0
Shareholders Equity	18.2	10.7	2.9	36.5	21.8

Last sale 18/03/2020	0.120
Recommendation	Buy (Spec)
Issued Capital	630.7
Market Cap	75.7

Valuation Ratios (A$m)	FY18	FY19	FY20e	FY21e	FY22e
Reported EPS (cps)	-1.7	-1.4	-1.2	-2.0	-1.8
Normalised EPS (cps)	-1.7	-1.4	-1.2	-2.0	-1.8
EPS growth (%)	-11%	nm	-9%	61%	-0.1
PE(x)	**nm**	**nm**	**nm**	**nm**	**nm**
EV/EBITDA (x)	-7.9	nm	nm	nm	nm
EV/EBIT (x)	-7.9	nm	nm	nm	nm
NTA (cps)	2.9	1.7	0.5	4.4	2.6
P/NTA (x)	0.0	0.1	0.3	0.0	0.0
Book Value (cps)	2.9	1.7	0.5	4.4	2.6
Price/Book (x)	0.0	0.1	0.3	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 %	150%	0%	0%	0%	0%
FCF yield %	-1127%	-1007%	-924%	-1400%	-1540%
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	-	175	400
USA	-	-	-
Australia/Asia Pacific	-	30	90
Total dose sales	**-**	**205**	**490**

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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