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Oncosil Medical (OSL)

ASCO Data Confirms OS Benefit

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

Recommendation
Buy (unchanged)
Price
$0.059
Valuation (12 months)
$0.20 (unchanged)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

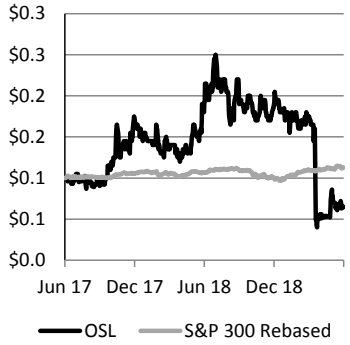
Expected Return	
Capital growth	**240%**
Dividend yield	**0%**
Total expected return	**240%**

Company Data & Ratios	
Enterprise value	**$31.7m**
Market cap	**$44.7m**
Issued capital	**630.7m**
Free float	**100%**
Avg. daily val. (52wk)	**$222,000**
12 month price range	**$0.02 - $0.26**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.06	0.18	0.19
Absolute (%)	3.2	-63.9	-65.8
Rel market (%)	2.4	-67.1	-72.2

Absolute Price



SOURCE: IRESS

Survival Data Is A Game Changer

Oncosil's recent poster presentation at the American Society of Clinical Oncology (ASCO) conference included significant new data which we believe should dispel the remaining doubts regarding the clinical benefit of Oncosil therapy in the treatment of locally advanced inoperable pancreatic cancer. The headline results drawn from 42 patients treated as per protocol in the PanCO study are as follows:

- Interim median overall survival (OS) of 16 months relative to the median 9 – 11 months under standard of care (SOC). This represents a gain of up to 7 months; and
- 1 year survival rate of 64% vs ~50% on SOC.

21 of 42 patients receiving Oncosil therapy remain alive at the time of the analysis, hence likely the survival benefit will continue to grow. The major survival benefit was seen in patients whose tumours where downsized and underwent surgical resection.

The safety profile of Oncosil therapy is unchanged. There were no serious or significant procedural complications. This survival data will form an essential component of the response to the British Standards Institute and Clinical Oversight Committee who had earlier denied a CE Mark. This survival data was not included in the original submission. We estimate the company has sufficient cash until early 2020, hence it is important that the CE Mark is resolved well before then.

Maintain Buy (Speculative) rating, Valuation

The CE mark remains the highest short term priority for the company. This survival data is highly compelling and we understand the data package for the CE Mark will also be supported by testimony from leading key opinion leaders in the field from the UK. We believe this will make it difficult for the regulator to deny a CE Mark, but nevertheless, the risk level around this decision remains high. BSI has already moved the goal posts once. We continue with our Buy (Speculative) rating and valuation of $0.20 which is unchanged. No changes to earnings.

Earnings Forecast

June Year End	FY18	FY19e	FY20e	FY21e
Revenues	4.4	3.0	3.7	7.3
EBITDA $m	-8.7	-9.7	-13.4	-12.9
NPAT (underlying) $m	-8.5	-9.2	-12.9	-12.4
NPAT (reported) $m	-8.5	-9.2	-12.9	-12.4
EPS underlying (cps)	-1.7	-1.5	-1.7	-1.6
EPS growth %	-11%	nm	13%	-4%
PER (x)	nm	nm	nm	nm
FCF yield (%)	nm	nm	nm	nm
EV/EBITDA (x)	-3.6	-3.3	-2.4	-2.4
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	-47.9%	-109.0%	-72.5%	-212.3%

SOURCE: BELL POTTER SECURITIES ESTIMATES

7 Month Extension in OS

Oncosil's recent poster presentation at the American Society of Clinical Oncology (ASCO) conference included significant new data which we believe should dispel the remaining doubts regarding the clinical benefit of Oncosil therapy in the treatment of locally advanced inoperable pancreatic cancer.

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- Interim median overall survival of 16 months relative to the median 9 – 11 months under standard of care (SOC). This represents a gain of up to 7 months; and
- 1 year survival rate of 64% vs ~50% on SOC.

SURGERY LEADS TO A SURVIVAL BENEFIT

21 of 42 patients receiving Oncosil therapy remain alive at the time the analysis was prepared, hence it is reasonably obvious the survival benefit will continue to grow.

The surgical resection rate of 24% (10 of 42) is higher than the estimated 15 – 20% rate using standard of care chemotherapy alone.

Of the 21 patients referred to above, 10 underwent surgical resection by Whipple procedure. Histopathological assessment confirmed RO surgical margin status in 8 patients and R1 status in 2 patients. The histology results are encouraging, RO means no evidence of cancerous tissue in the tissue surrounding the excised tumour. The prognosis for these patients is better, and indeed some may live for several years.

Previous clinical trials have also shown that surgical resection in locally advanced pancreatic cancer is associated with significantly longer median overall survival. We make this conclusion based on the data from a recent published study in ~80 patients who underwent a resection following chemotherapy[1]. Patients undergoing surgical resection had significantly better survival than patients who did not. Median OS: 35.3 months vs 16.3 months ($p<0.001$).

In recent weeks a published study by Rengelova et al[2] produced some relevant data. In this retrospective study, patients with either locally advanced pancreatic cancer (LAPC) or borderline resectable pancreatic cancer (BRPC) received neoadjuvant[3] therapy. The study established resected patients had better survival than non-resected patients (median survival 22.4 months vs 12.7months).

Patients in the PanCo study were not candidates for surgery at the time they commenced treatment, hence the correct benchmark for survival is in the range of 9 – 11 months.

Based on the work of Gemenetzis et al, we expect the co-hort of patients in PanCO who received surgical resection to achieve median overall survival of ~36 months.

Ultimately a randomised trial will be required to prove the survival benefit. The studies mentioned herein raise an interesting question for regulators. The quantum of the survival benefit from neoadjuvant therapy with surgery is so large (i.e. 35 months vs 9 to 11 months), that arguably all trial participants who become eligible for surgery should receive it. Any larger study is likely to allow for patients to cross over in these circumstances.

[1] Gemenetzis et al, Annals of Surgery, June 2018)

[2] Rangelova et al, Ann Surg 2019 April 2,

[3] Neoadjuvant therapy – in this setting, refers to chemotherapy designed to reduce the size of the tumour prior to surgical resection.

SAFETY

The safety profile of Oncosil therapy is unchanged. There were no serious or significant procedural complications. Patients reported the normal range of side effects associated with the chemotherapy.

CONCLUSIONS

There is no consensus on treatment for either LAPC or BRPC. We note the following conclusions by Shaib[4] et el on this topic from as recently as 2016:

- There is no consensus on the definitions of BRPC and LAPC which leads to major limitations is designing clinical trials and evaluating their results;
- The role of combination chemotherapy regimes in BRPC and LAPC remains an active area of investigation;
- There is no consensus on description of stages, treatment sequences (chemotherapy, chemoradiation or radiation) nor on the best chemotherapy regime.

As far are aware the standard of care chemotherapy is gemcitabine+abraxane. Clearly some oncologists have other preferred combinations and dosing regimes.

The data from PanCO on overall survival (released at ASCO) shows a clear survival benefit in those patients with LAPC where the tumour was able to be downsized with the patient becoming eligible for surgery. Although this data has not yet fully matured, it is strongly suggestive of a clinical benefit compared to chemotherapy alone (with no surgery). This is the basis upon which we believe the CE Mark may be given.

As to whether Oncosil+chemotherapy vs chemotherapy alone can improve the resection rate in LAPC or BRPC, this is a question for another day and a larger randomised study. The early evidence from PanCO suggests a small increase in the resection rate (i.e. 24% vs ~20% for chemotherapy alone).

The PanCO study will follow patients until at least July 2020 where upon the final survival data will eventually emerge.

The final CE Mark determination is yet to be made. The CE Mark filing is currently on hold pending a meeting between the company, the Clinical Oversight Committee and BSI. Following the release of this survival data, we believe there should be no further obstacle to the scheduling of a meeting wherein all parties will review the new data. In our view it is reasonable to expect this meeting to take place within 3 months i.e. by 31 August 2019.

OSL had cash of $10.2m as at 31 March. Net cash outflow from operations in the March quarter was $2.8m.

We believe this new survival data will make it difficult for the regulator to deny a CE Mark, but nevertheless the risk around this decision is high. BSI has already moved the goal posts once. We maintain our Buy (Speculative) recommendation and valuation of $0.20 which is unchanged.

[4] Shaib et el Oncologist 2016 Feb, 21(2) 178-87

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.

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. 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 phase III 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 required 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 Medical
as at 7 June 2019

Recommendation	Buy, Speculative
Price	$0.059
Valuation (12 months)	$0.20

Table 1 - Financial summary

Profit & Loss (A$m)	FY17	FY18	FY19e	FY20e	FY21e
Year Ending June					
Dose sales (units)	-	-	-	280	1,700
Net revenue from product sales	-	-	-	0.7	4.3
COGS	-	-	-	-0.1	-0.9
Gross profit	-	-	-	0.6	3.5
GP margin	50%	60%	80%	80%	80%
R&D incentive/Upfront receipts	3.4	4.4	3.0	3.0	3.0
Total revenues	**3.4**	**4.4**	**3.0**	**3.7**	**7.3**
Other expenses	**-10.8**	**-13.1**	**-12.7**	**-17.0**	**-19.4**
EBITDA	**-7.3**	**-8.7**	**-9.7**	**-13.4**	**-12.9**
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	-9.7	-13.4	-12.9
Sundry income	0.3	0.2	0.5	0.5	0.5
Pre tax profit	-7.0	-8.5	-9.2	-12.9	-12.4
Tax expense	-	-	-	-	-
NPAT- normalised	-7.0	-8.5	-9.2	-12.9	-12.4
Net abnormal items	-	-	-	-	-
Reported NPAT	-7.0	-8.5	-9.2	-12.9	-12.4

Cashflow (A$m)	FY17	FY18	FY19e	FY20e	FY21e
Gross cashflow	-8.6	-8.5	-8.2	-13.4	-12.7
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	-7.7	-12.9	-12.2
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	-6.2	-8.4	-7.8	-12.9	-12.2
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	1.0	15.6	0.0	22.5	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	(7.8)	9.6	(12.2)
Cash at beginning of period	9.8	8.0	15.2	7.4	16.9
Cash at year end	8.0	15.2	7.4	16.9	4.7

Balance Sheet (A$m)	FY17	FY18	FY19e	FY20e	FY21e
Cash	8.0	15.2	7.4	16.9	4.7
Receivables	3.5	4.5	3.0	3.0	2.7
Short term investments	-	-	-	-	-
Other current assets	0.2	0.1	0.1	0.1	0.1
Property, Plant and Equipment	0.1	0.1	0.1	0.2	0.2
Total assets	11.9	19.9	10.6	20.2	7.8
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	18.1	8.9	18.5	6.1
Share capital	36.7	52.3	52.3	74.8	74.8
Retained earnings	(30.5)	(39.0)	(48.3)	(61.2)	(73.6)
Reserves	4.0	4.9	4.9	4.9	4.9
Shareholders Equity	10.2	18.1	8.9	18.5	6.1

Last sale 06/06/2019	0.059
Recommendation	Buy (Spec)
Issued Capital	630.7
Market Cap	44.7

Valuation Ratios (A$m)	FY17	FY18	FY19e	FY20e	FY21e
Reported EPS (cps)	-1.5	-1.7	-1.5	-1.7	-1.6
Normalised EPS (cps)	-1.5	-1.7	-1.5	-1.7	-1.6
EPS growth (%)	-28%	-11%	nm	13%	0.0
PE(x)	**nm**	**nm**	**nm**	**nm**	**nm**
EV/EBITDA (x)	-4.3	-3.6	-3.3	-2.4	-2.4
EV/EBIT (x)	-4.3	-3.6	-3.3	-2.4	-2.5
NTA (cps)	2.1	2.9	1.4	2.4	0.8
P/NTA (x)	0.0	0.0	0.0	0.0	0.1
Book Value (cps)	2.1	2.9	1.4	2.4	0.8
Price/Book (x)	0.0	0.0	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 %	-2939%	-2293%	-2116%	-2828%	-2673%
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)	FY19e	FY20e	FY21e
Europe	-	140	1,400
USA	-	-	-
Australia/Asia Pacific	-	140	300
Total dose sales	**-**	**280**	**1,700**

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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The fact that the intellectual property base of a typical biotechnology company lies in science not generally regarded as accessible to the layman adds further to the riskiness with which biotechnology investments ought to be regarded. Clinical and regulatory risks are inherent in biotechnology stocks. Biotechnology developers usually seek US FDA approval for their technology which is a long and arduous three phase process to prove the safety, effectiveness and appropriate application or use of the developed drug and even after approval a drug can be the subject of an FDA investigation of subsequently discovered possible links between the drug and other diseases not previously diagnosed. Furthermore, the Australian exchange listed biotechnology sector is subject to influence by the global biotechnology sector, particularly that in the USA. Consequently, Australian exchange listed biotechnology stocks can experience sharp movements, both upwards and downwards, in both valuations and share prices, as a result of a re-rating of the sector both globally and in the USA, in particular. Investors are advised to be cognisant of these risks before buying such a stock.

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