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Oncosil Medical (OSL)

Now Screening For Patients

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
$0.115
Valuation
$0.42 (unchanged)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

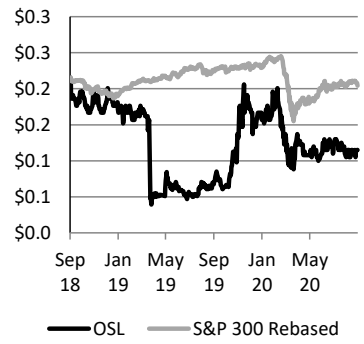
Expected Return	
Capital growth	**265%**
Dividend yield	**0.0%**
Total expected return	**265%**

Company Data & Ratios	
Enterprise value	**$74.3m**
Market cap	**$95.3m**
Issued capital	**828.6m**
Free float	**100%**
Avg. daily val. (52wk)	**$400,000**
12 month price range	**$0.05 - $0.21**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.12	0.11	0.06
Absolute (%)	-4.17	9.52	86.17
Rel market (%)	-3.56	6.22	94.32

Absolute Price



SOURCE: IRESS

Revenues Now Imminent

The company hosted an investor update today, the key points from which are as follows. 1) Leading hospitals in the UK are now screening for patients. By implication the funding issue has been resolved – at least in the short term. The company didn't elaborate on pricing or whether these were public or private patient being screened, nevertheless the key point is that first commercial revenues are now imminent. 2) Hospitals in the UK are now increasingly open for business as COVID restrictions ease. Restrictions on OSL team members accessing these hospital campuses has also eased, hence surgeon training can recommence 3) We expect a further update on survival for patients from the Panco study (being the approval study for Europe and the UK) later this calendar year. While the median survival is unlikely to move significantly, most of the 9 patients who underwent surgery following down staging of tumours remain alive today. 24% of patients in the study became eligible for surgery who otherwise would have had a life expectancy of only 8.5 months from diagnosis. A three year survival benefit for these patients is not unreasonable 4) OSL awaits the outcome of its Humanitarian Device Exemption (HDE) application to the FDA for the treatment of bile duct cancer. The period for the review process is 75 days, hence the outcome should be known in mid October. If successful the Oncosil therapy may be used immediately for the treatment of the disease in the US. The pathway for the use of Oncosil in the treatment of pancreatic cancer in the US remains unclear. A large randomised study will be required, all options remains open on the funding. If the HDE is granted, we believe off label use in locally advances pancreatic cancer is likely.

Investment View – Retain Buy (Speculative)

The company is well capitalised with cash of $21m. There are several important catalysts for the stock in the coming weeks and months as outlined above. In addition the delays to commercialisation from COVID are now easing, hence we are virtually certain of commercial revenues this year. No changes to earnings. Price target unchanged at 42c. Retain speculative (Buy) recommendation.

Earnings Forecast

June Year End	FY20	FY21e	FY22e	FY23e
Revenues	2.8	7.2	15.5	20.9
EBITDA $m	-4.4	-3.4	-7.6	-4.3
NPAT (underlying) $m	-4.3	-3.3	-7.5	-3.8
NPAT (reported) $m	-4.3	-3.3	-7.5	-3.8
EPS underlying (cps)	-0.7	-0.4	-0.9	-0.5
EPS growth %	-52%	-40%	128%	-48%
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 %	-20.0%	-18.1%	-67.5%	-59.0%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Revenues Imminent

ADDRESSABLE MARKET

We have now revised our estimate of total addressable market as follows:

Figure 1 – Total Addressable Market (TAM) Estimate

	Locally Advanced Pancreatic Cancer					Bile Duct	All Markets
	United Kingdom	European Union	USA	Australia	TAM	USA	TAM
Estimated Annual Incidence	8,700	79,000	48,000	4,300		8,000	
LAPC @ 40%	3,480	31,600	19,200	1,720			
Borderline resection	870	7,900	4,800	430			
Revenue per patient (local currency)	8,000	12,000	25,000	20,000		25,000	
FX Rate	0.54975	0.617575	0.7349	1.00		0.7349	
A$m	**63**	**768**	**816**	**43**	**1,690**	34	1,724

SOURCE: BELL POTTER SECURITIES ESTIMATES

In the UK, negotiations are underway for the treatment of patients in the NHS as well as via private hospitals. The private hospitals will support self pay and probably some reimbursement by private health insurance. Approximately 24% of London residents have PHI, hence this is a lucrative market.

Within the NHS, there are just 26 hospitals across the entire UK with the surgical facilities to perform the procedure. Specialist funding is likely available for a limited number of procedures each year.

In the US, assuming the Humanitarian Device Exemption (HDE) is successful the inclusion of this market adds an estimated $34m to the total addressable market. We are yet to include any sales for the bile duct market (cholangiocarcinoma) in the forecast as there is no launch plan at the moment and not a great of data with which to market the product. We expect initial uptake will be slow.

Investigator led studies in LAPC are likely in the US ahead of an approval study

The absence of a PMA for locally advanced pancreatic cancer (LAPC) in the US will not prevent early adopters from initiating investigator led clinical studies in pancreatic cancer, in fact, we believe this is likely once the HDE is approved. Ethics approval is likely given the data from Panco and the fact that the product is used in conjunction with the standard of care chemotherapy. If this is the case, the use of oncosil therapy for pancreatic cancer would be off label, however, given the survival benefit demonstrated in the Panco trial, US patients are likely to demand the treatment.

Reimbursement is another matter. If off label use in LAPC does proceed, self pay is likely in the first instance.

Many therapies are used off label in the US (including most of CSL's IGG products) for a variety of related conditions. The only catch is that the company cannot market the product off label, however, it can certainly present factual data at conferences (such as the survival data from the Panco study). OSL has been awarded breakthrough designation for the treatment of pancreatic cancer in the US.

The company is yet to discuss its regulatory pathway for LAPC in the US in any great detail. It has an IDE for pancreatic cancer. At least one clinical trial will be required (and probably only one), the nature and size of the trial are yet to be revealed.

We believe it is unlikely that OSL will gain a US approval on the basis of a post hoc literature review (as was the case for the CE Mark).

VALUATION

There are no changes to earnings. We retain our valuation of $0.42

Cash at 30 June 2020 was $21m. Based on our forecast the company has sufficient cash for a least two years, however, the forecasts is highly subjective with the key variables being the uptake rate for sales, marketing spend and R&D spend.

The forecast includes A$36m for a future US clinical study, however the nature of this remains uncertain, hence we retain our Buy (speculative) rating. Once the company begins to generate revenues in Europe some further funding options may arise including the sale of rights to Japan and China.

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 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 87,000 cases in Europe and 48,000 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 received the CE Mark to treat inoperable locally advance pancreatic cancer in April 2020. The US FDA granted an Investigational Device Exemption (IDE) in August 2016 and awarded Breakthrough designation in March 2020. 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 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 2 September 2020

Recommendation	Buy, Speculative
Price	$0.115
Valuation	$0.42

Table 1 - Financial summary

Profit & Loss (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Year Ending June					
Dose sales (units)	-	-	175	490	1,300
Net revenue from product sales	-	-	4.2	10.5	17.9
COGS	-	-	- 0.8	-2.1	-3.6
Gross profit	-	-	3.4	8.4	14.3
GP margin			80%	80%	80%
R&D incentive/Upfront receipts	3.6	2.8	3.0	5.0	3.0
Total revenues	**3.6**	**2.8**	**7.2**	**15.5**	**20.9**
Clinical trials	**-5.6**	**-3.7**	**-2.0**	**-12.0**	**-12.0**
Other expenses	**-6.7**	**-3.5**	**-7.8**	**-9.0**	**-9.6**
EBITDA	**-8.7**	**-4.4**	**-3.4**	**-7.6**	**-4.3**
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	-4.4	-3.4	-7.6	-4.3
Sundry income	0.2	0.1	0.1	0.1	0.5
Pre tax profit	-8.5	-4.3	-3.3	-7.5	-3.8
Tax expense	-	-	-	-	-
NPAT- normalised	-8.5	-4.3	-3.3	-7.5	-3.8
Net abnormal items	-	-	-	-	-
Reported NPAT	-8.5	-4.3	-3.3	-7.5	-3.8

Cashflow (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Gross cashflow	-7.7	-4.7	-0.9	-8.1	-5.9
Net interest	0.2	0.1	0.1	0.1	0.5
Other	0.0	0.1	0.0	0.0	0.0
Operating cash flow	-7.5	-4.5	-0.8	-8.0	-5.4
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	-7.5	-4.5	-0.8	-8.1	-5.4
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	0.0	17.9	0.0	0.0	0.0
Movement in borrowings	0.0	-0.1	0.0	0.0	0.0
Dividends paid	0.0	0.0	0.0	0.0	0.0
Change in cash held	(7.5)	13.3	(0.8)	(8.1)	(5.4)
Cash at beginning of period	15.2	7.7	21.0	20.2	12.1
Cash at year end	7.7	21.0	20.2	12.1	6.7

Balance Sheet (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Cash	7.7	21.0	20.2	12.1	6.7
Receivables	3.8	2.8	0.3	0.9	2.4
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	0.2	0.2
Total assets	11.7	24.0	20.7	13.3	9.4
Trade payables	0.8	1.8	1.8	1.8	1.8
Other provisions	0.2	0.3	0.3	0.3	0.3
Total Liabilities	1.0	2.1	2.1	2.1	2.1
Net Assets	10.7	21.9	18.6	11.2	7.3
Share capital	52.3	70.1	70.1	70.1	70.1
Retained earnings	(47.6)	(51.9)	(55.2)	(62.6)	(66.4)
Reserves	6.0	3.7	3.7	3.7	3.7
Shareholders Equity	10.7	21.9	18.6	11.2	7.4

Last sale 02/09/2020	0.115
Recommendation	Buy (Spec)
Issued Capital	828.6
Market Cap	95.3

Valuation Ratios (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Reported EPS (cps)	-1.4	-0.7	-0.4	-0.9	-0.5
Normalised EPS (cps)	-1.4	-0.7	-0.4	-0.9	-0.5
EPS growth (%)	nm	-52%	-40%	128%	-0.5
PE(x)	**nm**	**nm**	**nm**	**nm**	**nm**
EV/EBITDA (x)	nm	nm	nm	nm	nm
EV/EBIT (x)	nm	nm	nm	nm	nm
NTA (cps)	1.7	2.6	2.3	1.4	0.9
P/NTA (x)	0.1	0.0	0.1	0.1	0.1
Book Value (cps)	1.7	2.6	2.3	1.4	0.9
Price/Book (x)	0.1	0.0	0.1	0.1	0.1
DPS (cps)	-	-	-	-	-
Payout ratio %	0%	0%	0%	0%	0%
Dividend Yield %	0.0%	0.0%	0.0%	0.0%	0.0%
Franking %	160%	0%	0%	0%	0%
FCF yield %	-1051%	-483%	-84%	-849%	-567%
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)	FY21e	FY22e	FY23e
Europe	175	400	1,000
USA	-	-	-
Australia/Asia Pacific	-	90	300
Total dose sales	**175**	**490**	**1,300**

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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