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Oncosil Medical (OSL)

First UK Revenues Soon

Speculative
See key risks on Page 3 and Biotechnology Risk Warning on Page 5. Speculative securities may not be suitable for Retail Clients.

Recommendation
Buy (unchanged)
Price
$0.105
Target (12 months)
$0.42 (unchanged)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

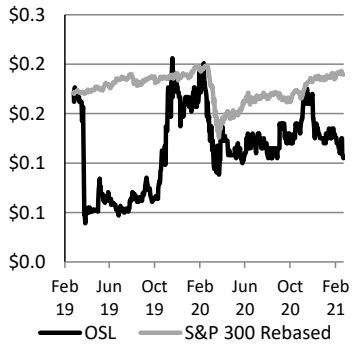
Expected Return	
Capital growth	**300%**
Dividend yield	**0.0%**
Total expected return	**300%**

Company Data & Ratios	
Enterprise value	**$66.8m**
Market cap	**$84.8m**
Issued capital	**807.3m**
Free float	**100%**
Avg. daily val. (52wk)	**$434,000**
12 month price range	**$0.105 - $0.18**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.13	0.17	0.17
Absolute (%)	-16.00	-36.36	-37.01
Rel market (%)	-16.65	-41.01	-32.88

Absolute Price



SOURCE: IRESS

Further Milestones Within Reach

The milestone event for Oncosil during 1H21 was unquestionably the treatment of the first commercial patient. Based on total revenues of $93K, we estimate there were two further patients in 1H21. While this is a humble beginning, it is a beginning nonetheless. We firmly believe the clinical data will support broader adoption in the months ahead.

OSL generated a net loss for the 6 months to December of $4.8m and net cash outflow from operations of $3.2m. Cash at the end of the period was $18m.

In the months ahead further sales are likely in the UK where 9 hospitals in the London area are now on the cusp of screening for patients. The roll out of the COVID vaccine is also welcome news. Approximately 20% of the UK population has now received at least one dose of vaccine with the rate of new infections plummeting. The company recently confirmed that it expects to book first UK revenues before 30 June 2021. In Australia, TGA approval is also probable prior to the end of FY21 with hospitals in Adelaide and Melbourne likely to become early adopters.

The commercial launch of Oncosil therapy is not supported by data from a randomised controlled trial. Despite this, the comprehensive documentation review which led to the CE Mark is not insignificant data. The analysis concluded a clear survival benefit for patients treated with Oncosil when combined with chemotherapy compared to a range of chemotherapy regimes alone. Elsewhere OSL will complete an updated Humanitarian Device Exemption application for the treatment of Bile Duct cancer in the US with the results of that application known later this year.

Investment View: Maintain Buy, Valuation $0.42

There are no significant earning changes in the forecast period. Important catalysts are approaching in both the UK and Australia, such that we are confident that revenues will accelerate over the remainder of the calendar year. We maintain our Buy (Speculative) rating and valuation of $0.42.

Earnings Forecast

June Year End	FY20	FY21e	FY22e	FY23e
Revenues	2.8	5.9	16.6	23.0
EBITDA $m	-4.4	-4.4	-6.7	-2.6
NPAT (underlying) $m	-4.3	-4.3	-6.6	-2.1
NPAT (reported) $m	-4.3	-4.3	-6.6	-2.1
EPS underlying (cps)	-0.7	-0.5	-0.8	-0.3
EPS growth %	na	na	na	na
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%	-25.2%	-60.5%	-29.5%

SOURCE: BELL POTTER SECURITIES ESTIMATES

9 London hospital on the cusp for screening

Oncosil has now transformed into a commercial stage biotech company. Revenues for 1H21 were $93K representing a modest start to the commercial sale of Oncosil, nevertheless, COVID driven access to hospitals in markets around the globe were a major anchor to the commercial launch.

The key points from last week's market update were as follows:

- Interest in the Oncosil therapy amongst interventional oncologists in the UK and Germany remains high, notwithstanding long delays in the finalisation of local regulatory matters;
- COVID has severely restricted access to hospitals in the UK and Germany as well as to regulators; and
- The company has completed all the major appointments for its commercial team in Europe.

The Osprey registry (for the compulsory post market approval performance study) finally received ethics approval from the Health Research Authority (HRA) and the Research Ethics Committee (REC) both in the UK. This had been delayed by a patient consent issue.

There are 9 hospitals in London which have now received the appropriate licenses to use radioactive phosphorous (i.e. the Oncosil therapy). The company had previously announced that 5 or the 9 sites in the UK have received training, ready begin to use the Oncosil device.

The matters requiring finalisation with UK hospitals are now limited to commercial terms. We expect OSL will focus on the private pay market initially followed by publically funded cases. We also expect some pockets of funding will be available from certain NHS Trusts for public patients.

With regulatory matters now finally in hand, hospitals in the UK are now very close to being able to commence screening for patients. Consequently, the company believes first commercial revenues in the UK will be invoiced prior to 30 June 2021.

The severity of the COVID pandemic is also beginning to ease with the roll out of the COVID vaccine in the UK continuing and accelerating. As of 14 February, 12.2m persons in the UK had received at least one dose of vaccine including ~2m persons in the last week. The vaccination program along with the weeks of lockdown has seen the infection rate drop back to ~10,000 per day, the lowest since October 2020 prior to the second wave. As warmer weather approaches the incidence of the pandemic is likely to continue to ease, reducing pressure on hospitals and allowing other treatments to resume.

Our revenue expectations for FY21/FY22 remain very modest. First commercial revenues have now been secured (in NZ) and further sales are probable in the UK, NZ and potentially Australia over the coming months. There is no need to amend our revenue forecast at this time.

In Australia, we estimate the total market at ~2,000 patients annually with an estimated 90 patients in the first full year following a product launch.

The company remains well capitalised with $18m of cash. We maintain our Buy – Speculative rating. Valuation remains $0.42

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 23 February 2021

Recommendation	Buy, Speculative
Price	$0.105
Target (12 months)	$0.42

Table 1 - Financial summary

Profit & Loss (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Year Ending June					
Dose sales (units)	-	-	23	290	800
Net revenue from product sales	-	-	2.9	11.6	20.0
COGS	-	-	0.6	-2.3	-4.0
Gross profit	-	-	2.3	9.3	16.0
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**	**5.9**	**16.6**	**23.0**
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**	**-4.4**	**-6.7**	**-2.6**
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	-4.4	-6.7	-2.6
Sundry income	0.2	0.1	0.1	0.1	0.5
Pre tax profit	-8.5	-4.3	-4.3	-6.6	-2.1
Tax expense	-	-	-	-	-
NPAT- normalised	-8.5	-4.3	-4.3	-6.6	-2.1
Net abnormal items	-	-	-	-	-
Reported NPAT	-8.5	-4.3	-4.3	-6.6	-2.1

Cashflow (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Gross cashflow	-7.7	-4.7	-1.7	-7.6	-4.4
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	-1.6	-7.5	-3.9
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	-1.7	-7.6	-3.9
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	(1.7)	(7.6)	(3.9)
Cash at beginning of period	15.2	7.7	21.0	19.3	11.7
Cash at year end	7.7	21.0	19.3	11.7	7.8

Balance Sheet (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Cash	7.7	21.0	19.3	11.7	7.8
Receivables	3.8	2.8	0.1	1.1	2.8
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	19.7	13.1	11.0
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	17.6	11.0	8.9
Share capital	52.3	70.1	70.1	70.1	70.1
Retained earnings	(47.6)	(51.9)	(56.2)	(62.8)	(64.9)
Reserves	6.0	3.7	3.7	3.7	3.7
Shareholders Equity	10.7	21.9	17.6	11.0	8.9

Last sale 23/02/2021	0.105
Recommendation	Buy (Spec)
Issued Capital	807.3
Market Cap	84.8

Valuation Ratios (A$m)	FY19	FY20	FY21e	FY22e	FY23e
Reported EPS (cps)	-1.4	-0.7	-0.5	-0.8	-0.3
Normalised EPS (cps)	-1.4	-0.7	-0.5	-0.8	-0.3
EPS growth (%)	nm	na	na	na	na
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	2.1	1.3	1.1
P/NTA (x)	0.1	0.0	0.0	0.1	0.1
Book Value (cps)	1.7	2.6	2.1	1.3	1.1
Price/Book (x)	0.1	0.0	0.0	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 %	-1151%	-529%	-191%	-870%	-452%
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	21	200	500
USA	-	-	-
Australia/Asia Pacific	2	90	300
Total dose sales	**23**	**290**	**800**

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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