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Oncosil Medical (OSL)

Commercial Validation Awaits

Speculative

See key risks on Page 5 and Biotechnology Risk Warning on Page 7. Speculative securities may not be suitable for Retail Clients.

Recommendation
Buy (unchanged)
Price
$0.11
Valuation
$0.42 (previously $0.38)
Risk
Speculative

GICS Sector

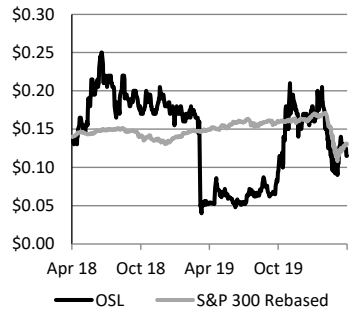
Healthcare Equipment and Services

Expected Return	
Capital growth	**282%**
Dividend yield	**0.0%**
Total expected return	**282%**
Company Data & Ratios	
Enterprise value	**$62.4m**
Market cap	**$69.4m**
Issued capital	**630.7m**
Free float	**100%**
Avg. daily val. (52wk)	**$303,000**
12 month price range	**$0.05 - $0.21**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.09	0.18	0.05
Absolute (%)	23.7	-34.3	121.2
Rel market (%)	13.9	-13.6	133.4

Absolute Price



SOURCE: IRESS

First Revenue Likely in 2020

OSL received the CE Mark for its Oncosil therapy for the treatment of inoperable locally advanced pancreatic cancer earlier in April as anticipated. The CE Mark allows the company to commence the commercial sale of the device in the UK, Europe and numerous other countries around the world (excluding the US, Japan and China). The CE Mark follows the Breakthrough Designation with the US FDA in March 2020.

We estimate the addressable market in locally advanced pancreatic cancer as being at least A$1.2bn with the potential for significant label expansion into other disease including primary liver cancer as well as off label use in bile duct cancer and for down staging of borderline surgical patients in pancreatic cancer. Oncosil therapy is the first significant breakthrough in the treatment of pancreatic cancer since the approval of the chemotherapy agent Abraxane in 2013.

This report reviews the survival data to emerge from the PanCo study which underpinned both the CE Mark and Breakthrough Designation.

We expect Oncosil will be launched in the UK and Europe later this calendar year in at least 12 hospitals, quickly expanding to 20. Average revenue per case is expected to exceed A$20,000, hence once momentum builds we anticipate OSL will rapidly exceed $10m in annual revenues. Over the next year we also expect the company to advance plans for a randomised clinical trial in the US. Based on the outcomes from the PanCo study which demonstrated a clear survival benefit, and assuming similar results are achieved in a US pivotal study, Oncosil appears destined to become the standard of care for locally advanced pancreatic cancer.

Valuation Raised to $0.42

Based on the demonstrated survival benefit, we believe Oncosil therapy will achieve commercial validation shortly following launch. Valuation is raised to $0.42 and we maintain our Speculative Buy recommendation.

Earnings Forecast

June Year End	FY19	FY20e	FY21e	FY22e
Revenues	3.6	3.6	6.7	13.7
EBITDA $m	-8.7	-7.9	-16.5	-13.2
NPAT (underlying) $m	-8.5	-7.7	-16.4	-13.1
NPAT (reported) $m	-8.5	-7.7	-16.4	-13.1
EPS underlying (cps)	-1.4	-1.2	-2.0	-1.6
EPS growth %	nm	-9%	61%	-20%
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%	-56.6%

SOURCE: BELL POTTER SECURITIES ESTIMATES

CE Mark Secured

Following the awarding of the CE Mark we take the opportunity to revisit the key data from the Panco study. The study dosed 42 subject with locally advanced pancreatic cancer and the key data points are outlined below.

This clinical data will be used by the company in its marketing pitch across Europe in the months ahead and it is also the data responsible for the Breakthrough Designation in the US.

The comparative data on each of the efficacy measures is extracted from an extensive literature review conducted by the company as part of CE Mark submission to the BSI[1].

Figure 1 - Oncosil therapy - key efficacy measures vs retrospective literature review data

	Oncosil + Chemotherapy (per protocol)	95% CI	Chemotherapy only	Induction Chemo and Consolidation Chemoradiotherapy	All treatments
Overall Survival (months)	**16.0**	**11.1, NC**	**12.7**	**12.6**	**12.7**
Progression Free Survival (months)	9.3	7.2 - 12.2	6.6	7.6	7.6
Local disease control rate (week 24)	100%	91.6 - 100	71.3%	na	88.5%
Resection rates %	23.8%	12.1 - 39.5	7.7%	na	11.5%

SOURCE: COMPANY DATA

In relation to surgical resection:

10 implanted study participants in the Panco study were restaged and subsequently had surgical resection with curative intent. Of these subjects, 8 had R0 surgical margins which indicates no detectable cancerous cells in the tissue surrounding tumour following excision.

Surgical resection in LAPC is critical, improving the 5 year survival rate from 5% to 20%.

Based on this summary data we note the following key points:

- Firstly, the state of the art therapy is defined by clinical practice guidelines as set out by the European Society of Medical Oncology (ESMO), American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN). The NCCN guidelines in particular offer numerous options for chemotherapy regimens.
- Across all guidance, the standard for locally advanced pancreatic cancer are induction chemotherapy, chemotherapy and consolidation chemo radiotherapy.

OVERALL SURVIVAL

The gold standard for efficacy is overall survival benefit. In figure 1, overall survival in the Oncosil group was measured across 42 patients all of whom were implanted with Oncosil (being the treatment per protocol group). Relative to the standard of care the overall survival (OS) benefit is approximately 3.3 months. Even though the PanCo study was not randomised, the investigators estimate a pro-forma p-value (vs the patients in the literature review) of 0.001 which is highly statistically significant.

[1] BSI – British Standard Institute

The extension in overall survival (being approximately a 26% extension from the SOC) is an outstanding outcome and the data is still maturing. The long term survival data is yet to be published as we understand many of the patients are still alive.

Progression free survival (PFS) is a commonly used proxy for overall survival in cancer trials (before the OS data has matured). Several drugs have been awarded accelerated approval by the FDA on the basis of a meaningful extension in PFS. These approvals are typically subject confirmatory studies and an overall survival benefit. In this case the PFS data is of limited significance as the interim OS data is available.

RESECTION RATE

The resection rate is a measure of patients first classified as inoperable, who are later reclassified/down staged and become suitable for surgery (following initial treatment). Under the current standard of care (SOC), the resection rate is between 7 – 11%, relative to the Oncosil regime at ~24% (i.e. more than double SOC).

The resection rate is significant because of the survival benefit associated with the surgery. Key data from the literature review shows that patients undergoing surgical resection had significantly better survival than patients who did not. Median overall survival was 35.3 months vs 16.3 months and three year survival rates of 50% vs 11% (p<0.001).

Based on the PanCo study, the Oncosil regime appears to be a highly effective treatment for down staging inoperable tumours such that they become operable.

ADDRESSABLE MARKET

The CE Mark is for inoperable locally advanced pancreatic cancer (LAPC).

We estimate the total addressable market as follows:

Figure 2 – Total Addressable Market (TAM) Estimate

LAPC	United Kingdom	European Union	United States	Australia	TAM
Estimated Annual Incidence	8,700	79,000	48,000	3,350	
Locally Advanced Pancreatic Cancer Patients @ 40%	3,480	31,600	19,200	1,340	
Revenue per patient (local currency)	8,000	12,000	25,000	20,000	
FX Rate	0.5093	1.1505	0.637	1.00	
A$m	**55**	**330**	**754**	**27**	**1,165**

SOURCE: BELL POTTER SECURITIES ESTIMATES

The calculation excludes Japan and China both of which are large markets. China for example is estimated to have more than 65,000 cases annually. Japan is also likely to require a small local trial prior to an approval. We expect the company to partner the Oncosil therapy in both jurisdictions.

Our estimated addressable market of A$1.1bn includes only the market for locally advanced pancreatic cancer (LAPC - the form of the disease which is inoperable and has not yet spread to other organs outside of the pancreas) which represents 30-40% of all cases.

The aim with this patient group is to downstage the cancer such that the patients become eligible for surgery, hence the focus on resection rates.

The largest market segment is those with metastatic disease. Typically these patients are treated with a variety of chemotherapy regimens, however, the prognosis for them is poor. This group was excluded from the PanCo study and is also unlikely to be funded by any insurer or public body, nevertheless it is not inconceivable that self-pay patients may be willing to try off label treatment in conjunction with a regime of chemotherapy. We exclude this group from the estimate of TAM.

Other off label treatment groups are those with borderline resectable cancers as well as those with bile duct cancer (which is the subject of humanitarian device exemption) in the US.

FUNDING

Funding for Oncosil therapy will come from a variety of sources depending upon the country and the patient. Initially in Europe and the UK we expect a mix of public funding and private pay. The company is working with advisors to secure various pockets of funding from the NHS in the UK as well as regional health authorities in Europe. Further funding many be available as data from a large randomised clinical trial becomes available.

Funding for any new therapy in Europe is challenging, nevertheless the data from the literature review is so overwhelmingly one sided in favour of Oncosil therapy relative to the standard of care, we expect that patient advocacy groups and the oncology community will be strongly supportive of this therapy.

OSL is likely to conduct a health economics study to justify higher pricing in the US. Our initial forecast is for the US market is set with the price of US$30,000. This is likely to be a conservative first estimate.

LAUNCH TIMETABLE

We expect OSL will launch Oncosil therapy later this year once the COVID19 crisis has passed and staff are able to access hospitals. In the interim the company is preparing numerous local country product registrations including for the Asia Pacific region. The CE mark is recognised in most countries except for the US, China and Japan. We expect at least a dozen hospitals initially across the UK and other key markets in Europe expanding to ~20 sites within 12 months.

The outlook for revenue generation across just 20 sites is attractive. At one to two procedures per month per site, the revenues quickly exceed A$1m/month and growing.

OSL is currently funded for a limited launch in Europe, however, as utilisation grows the company is likely to require further working capital.

SUMMARY OF EARNINGS CHANGES

Figure 3 - 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	6.7	1%	13.7	11.8	16%
EBITDA	-7.9	-7.9	0.6%	-16.5	-16.5	0%	-13.2	-14.8	11%
NPAT	-7.7	-7.7	-0.6%	-16.4	-16.4	0%	-13.1	-14.8	11%
EPS	-1.2	-1.2	-3.4%	-2.0	-2.0	0%	-1.6	-1.8	12%

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

First meaningful revenues from product sales are due in FY21. Valuation is modestly upgraded from $0.38 to $0.42 and we maintain our speculative Buy 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 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 is 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 20 April 2020

Recommendation	Buy, Speculative
Price	$0.11
Valuation	$0.42

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	8.7
COGS	-	-	- 0.1	-0.7	-1.7
Gross profit	-	-	0.5	3.0	6.9
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**	**13.7**
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**	**-13.2**
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	-13.2
Sundry income	0.2	0.2	0.1	0.1	0.1
Pre tax profit	-8.6	-8.5	-7.7	-16.4	-13.1
Tax expense	-	-	-	-	-
NPAT- normalised	-8.6	-8.5	-7.7	-16.4	-13.1
Net abnormal items	-	-	-	-	-
Reported NPAT	-8.6	-8.5	-7.7	-16.4	-13.1

Cashflow (A$m)	FY18	FY19	FY20e	FY21e	FY22e
Gross cashflow	-8.5	-7.7	-7.0	-13.9	-13.7
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	-13.6
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	-13.7
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	(13.7)
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	23.2

Balance Sheet (A$m)	FY18	FY19	FY20e	FY21e	FY22e
Cash	15.2	7.7	0.7	36.9	23.2
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	24.4
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	23.4
Share capital	52.3	52.3	52.3	102.3	102.3
Retained earnings	(39.1)	(47.6)	(55.3)	(71.8)	(84.9)
Reserves	5.0	6.0	6.0	6.0	6.0
Shareholders Equity	18.2	10.7	2.9	36.5	23.4

Last sale 17/04/2020	0.110
Recommendation	Buy (Spec)
Issued Capital	630.7
Market Cap	69.4

Valuation Ratios (A$m)	FY18	FY19	FY20e	FY21e	FY22e
Reported EPS (cps)	-1.7	-1.4	-1.2	-2.0	-1.6
Normalised EPS (cps)	-1.7	-1.4	-1.2	-2.0	-1.6
EPS growth (%)	-11%	nm	-9%	61%	-0.2
PE(x)	**nm**	**nm**	**nm**	**nm**	**nm**
EV/EBITDA (x)	-7.2	nm	nm	nm	nm
EV/EBIT (x)	-7.2	nm	nm	nm	nm
NTA (cps)	2.9	1.7	0.5	4.4	2.8
P/NTA (x)	0.0	0.1	0.2	0.0	0.0
Book Value (cps)	2.9	1.7	0.5	4.4	2.8
Price/Book (x)	0.0	0.1	0.2	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 %	-1230%	-1099%	-1008%	-1527%	-1510%
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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