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Oncosil Medical (OSL)

First Patient Revenues

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
$0.135
Target (12 months)
$0.42 (unchanged)
Risk
Speculative

GICS Sector

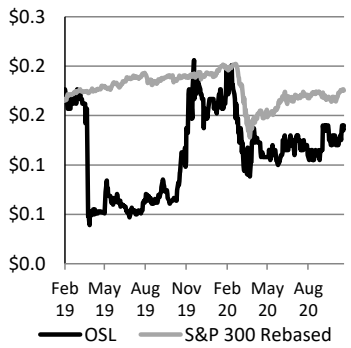
Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	**211%**
Dividend yield	**0.0%**
Total expected return	**211%**
Company Data & Ratios	
Enterprise value	**$90.9m**
Market cap	**$111.9m**
Issued capital	**828.6m**
Free float	**100%**
Avg. daily val. (52wk)	**$454,000**
12 month price range	**$0.08 - $0.21**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.14	0.12	0.08
Absolute (%)	3.70	21.74	67.98
Rel market (%)	-0.14	19.17	75.85

Absolute Price



SOURCE: IRESS

First Commercial Revenues

Following years of development Oncosil Medical has now successfully delivered its first ever dose of therapy to a paying customer in New Zealand. This event is a major milestone for the company which now has aspirations to rapidly expand the use of Oncosil in the treatment of locally advanced pancreatic cancer (LAPC). All the initial patients to receive therapy are self pay and while OSL did not disclose its revenue from this first patient, we estimate it would have been in the range of US$20 - US$25K.

Oncosil therapy is now approved throughout Europe, NZ, Singapore and Malaysia. Within these markets the largest single market is the UK where we expect the company will also shortly treat its first commercial patient. The UK market is estimated to be worth up to US$115m annually.

Upcoming catalysts for the stock include regulatory approval for Australia and Hong Kong and potentially granting of the humanitarian device exemption (HDE) for entry into the US market for the treatment of bile duct cancers. The US market for bile duct cancer is estimated at US$80m at an indicative list price in the US of US$50K per patient.

Elsewhere, the company recently provided an update on the clinical data from the Panco study. The new data concerns the patient sub group which became eligible for curative surgery following down staging of their tumours after treatment with Oncosil therapy. 14 patients became eligible for surgery representing 33% of participants. There is a very significant survival benefit associated with the surgery if patients can be restaged. This new data will be key to the company's marketing efforts in Europe which are now under way, in addition to a key focus in a potential approval study for the United States.

Investment View – Maintain Buy (Speculative)

First commercial revenues is a major milestone. We expect significant acceleration in revenue over the next 24 months. Although the changes to revenues and EPS in FY21 - FY23 are large in percentage terms, the actual dollar amounts are considered immaterial in terms of the overall value of the company and its market capitalisation. Valuation is maintained at $0.42. Buy (Speculative) recommendation is maintained.

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

Commercialisation Commences

Key data from AGM Update

CLINCAL DATA UPDATE FROM PANCO

Of the 10 patients that were down staged and under went potentially curative surgery, 6 remain alive with a survival range of 26 – 35 months. The overall survival data (OS) data for this group continues to mature. The other 4 patients have passed away with survival ranging between 18.8 – 22.1 months.

The median overall survival from a recent retrospective analysis of patients with LAPC who under went surgery is 35 months[1]. In our view the data from the Panco study participants is on track to match the 35 months survival.

In the same retrospective analysis, patients who did not undergo surgery (because they never became eligible) survived on average 16.3 months which is comparable to the median 16 month survival in Panco.

We conclude there is little doubt that conversion of patient's with inoperable cancer at diagnosis to becoming operable is associated with a distinct survival benefit.

Where to Now?

There are reams of data and studies concerning the treatment of pancreatic cancer over the last decade. The answer as to which is the best treatment is never straight forward and the absence of a large randomised trial in patients with locally advanced disease does not help.

In this section we consider how a future randomised clinical study by OSL may look starting with the key data from the Panco study.

A CLOSER LOOK AT PANCO

In the Panco Study, 14 of 42 (33%) patients became eligible for surgery following neoadjuvant chemotherapy (i.e. chemotherapy treatment prior to surgery). This is well ahead of the rate noted in previous studies included in the 2019 literature review where the resection rate across all papers was ~11%. Of the 14 patients in the Panco study, 10 actually under went the surgery, while the remaining 4 were not well enough.

Also apparent is the wide range of treatment methodologies between various hospitals and countries. There are multiple points of variation in the treatment of inoperable LAPC patients between hospitals let alone depending on which country the patient is seeking treatment and their capacity to pay for therapy.

In our view the absence of a uniform treatment protocol creates a significant opportunity for Oncosil. Some of the key points of variation in treatment include:

- the period of neoadjuvant chemotherapy (ranging from a few weeks to 5 months);
- the use of external beam therapy; and
- the type of chemotherapy used (there are multiple combinations in use around the world).

Patients in the Panco study received either gemcitabine + abraxane (aka nab paclitaxel) or Folforinox.

- 34 patients received gemcitabine + abraxane for an average of 5 cycles over a median duration of 147 days;

[1] Gemenetzis – Survival in LAPC after neoadjuvant therapy and surgical resection Ann. Sug 2019, 270(2) 340 - 347

- 8 patients received received Folforinox for an average of 6 cycles over a median duration of 90 days;
- None of the patients received external beam therapy.

The median of 16 months survival (covering all patients regardless of whether or not they received surgery) in Panco is comparable to the results from one of the best hospitals in the United States – being Johns Hopkins (Baltimore).

Johns Hopkins was the US hospital responsible for generating the data in the Gemenetzis paper referred to in the footnotes. In our opinion this is a seminal research piece for a few reasons:

- Johns Hopkins is a leading cancer centre in the United States;
- Large patients numbers were involved (n = 415), all confirmed as inoperable LAPC, and the vast majority with EOCG status of 0 or 1, hence practically identical to the patient population in Panco;
- The Gemenetzis study group also excluded borderline inoperable cases as did Panco;
- Patients received neoadjuvant chemotherapy for an average of 5 months and were then evaluated for surgical resection. Approximately 20% of patients (n = 84) under went the surgery.

The investigators in this retrospective study then stratified the population into those who underwent surgery (resected) and non resected.

The non resected group achieved median survival of 16.3 months compared to the median of the literature review of 12.7 months. This is a meaningful difference and probably attributable to the skill and care levels the patients received as well as the disease state in patients at the start of treatment.

The investigators in Gemenetzis also concluded that OS was not associated with the type of chemotherapy regime. This is a key point that is well substantiated by the data.

As we have previously discussed the resected patient group achieved a median survival of 35 months.

The data from the Gemenetzis trial was highlighted by the OSL in its 2019 AGM presentation (page 33).

Next Clinical Trial Design Considerations

US approval for the use of Oncosil in the treatment of pancreatic cancer will require at least one large randomised, controlled study. The company has not committed to any further clinical studies at this time, hence the following discussion is theoretical. The target patient group at least is easy to define – inoperable LAPC, excluding borderline cases. This mimics the patient group in Panco.

The remainder is more difficult and the Scientific Advisory Board together with the Chief Medical Officer have important decisions to make regarding the neo-adjuvant chemotherapy regime (one or more) and the point at which to implant the Oncosil therapy. No two patients react the same to chemotherapy and for this reason the decisions on the type and duration of the chemotherapy are normally made by the treating oncologist as part of a multi disciplinary team on site at the hospital. These factors need to be incorporated into the trial design.

The study may consider stratifying patients between non resectable and resectable.

Primary endpoint is likely to include overall survival in addition to the rate at which patients become eligible for surgery. The data consistently shows that the surgery is clearly

associated with a long term survival benefit and this is where we believe the FDA will require OSL to focus.

For those patients who do not achieve surgical re-section, OS is the logical endpoint.

The Panco data suggests that both the rate of re-section (surgery) and OS in the non-resection cohort are comfortably ahead of the rates achieved in most hospitals under most oncologists.

The other key factor in the design is the randomisation. Any skew of the trial in terms of patient age, sex, tumour size, ECOG status could derail the study.

European Commercialisation

Oncosil obtained the CE mark earlier this year and is now well advanced in its commercialisation. But for the COVID crisis in Europe it is likely the company would have already treated a first patient.

The company has made significant in-roads towards commercialisation including the following key points:

- 9 person sales force now in place covering UK, Germany, Italy and Benelux;
- Central radio pharmacy established and contracted to service 15 hospitals in the London area;
- Multiple hospitals in London now undergoing training and certification;
- Osprey patient registry now operationally ready. This is a key registry to support on going use of the product. It will provide essential data on the treatment and outcomes of each patient receiving Oncosil therapy;
- Oncologist across Europe also tend to use a range of chemotherapy regimes, however, for any number of reason the survival data tends to be well below that seen in the Gemenetzis study from Johns Hopkins. The three to four month survival benefit across all patients together with the increased rate of resection achieved in the Panco study make compelling reasons to use Oncosil.

We maintain our valuation at $0.42. Recommendation is maintained at Buy (Speculative).

Figure 1 - Summary of earnings changes

	2021			2022			2023		
	New	Old	% change	New	Old	% change	New	Old	% change
Revenues	5.9	7.2	-17.7%	16.6	15.5	7%	23.0	20.9	10%
EBITDA	-4.4	-3.4	-30.5%	-6.7	-7.6	12%	-2.6	-4.3	39%
NPAT	-4.3	-3.3	-31.3%	-6.6	-7.5	12%	-2.1	-3.8	44%
EPS	-0.5	-0.4	-30.7%	-0.8	-0.9	12%	-0.3	-0.5	49%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Although the changes to revenues and EPS in FY21 - FY23 are large in percentage terms, the actual dollar amounts are considered immaterial in terms of the overall value of the company and its market capitalisation.

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 22 October 2020

Recommendation	Buy, Speculative
Price	$0.135
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 22/10/2020	0.135
Recommendation	Buy (Spec)
Issued Capital	828.6
Market Cap	111.9

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	0.1	0.1	0.1	0.1
Book Value (cps)	1.7	2.6	2.1	1.3	1.1
Price/Book (x)	0.1	0.1	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 %	-896%	-411%	-148%	-677%	-352%
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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