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OncoSil Medical (OSL)

10 Centres Now Recruiting

Speculative
Refer to key risks on page 4 and Biotechnology Risk Warning on page 7. Speculative securities may not be suitable for retail clients.

Recommendation
Buy (unchanged)
Price
$0.088
Valuation
$0.41 (previously $0.39)

GICS Sector

Healthcare Equipment and Services

Expected Return	
Capital growth	**365%**
Dividend yield	**0.0%**
Total expected return	**365%**

Company Data & Ratios	
Enterprise value	**$34.9m**
Market cap	**$42.9m**
Issued capital	**487m**
Free float	**100%**
Avg. daily val. (52wk)	**$90,000**
12 month price range	**$0.076 - $0.18**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.09	0.13	0.13
Absolute (%)	-1.61	-26.80	-26.80
Rel market (%)	-1.77	-24.29	-29.89

13 Patients Now Enrolled In Onco Pac 1

Progress on the recruitment of this pivotal study accelerated during the June quarter and in July with 13 patients now enrolled. A further 7 patients are required for the agreed 20 patient run in and submission of the data package for CE Mark accreditation. While the outcomes from the data are by no means certain, Oncosil has stated that procedure outcomes are consistent with the past. In our view this is strongly suggestive of some promising results for these patients.

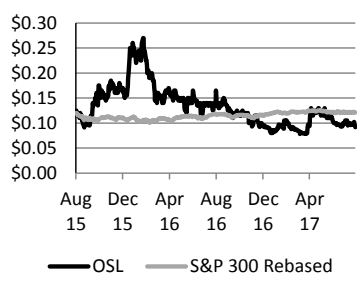
Despite progress in patient recruitment, the Board of Oncosil has provided what is in our view conservative guidance on the CE Mark Update. The company acknowledges recruitment has been more difficult and slower than anticipated and that an acceleration in recruitment is required in order to allow sufficient time for the Notified Body to make a decision (on approval) by the end of 2017. Nevertheless we believe recruitment of the first 20 patients will be complete by mid September, which should allow submission and review time (of the data) in advance of year end. The key variable (other than the clinical results) will be the BSI (the Notified Body) which does not have mandated response requirements.

In addition the US FDA has agreed to a modest relaxation of patients required for its 20 patient run in. Half of these may now receive treatment in non US centres. This is a small but meaningful concession.

Cash Reserves Likely Sufficient to CE Mark

The cash burn rate for the June quarter was $2.37m and the company had $8.0m in cash at period end which is well ahead of the anticipated $6.7m in our previous forecast. We expect OSL has sufficient cash to complete the recruitment of the 20 patient run in study and submit a data package. Ideally the company will have a CE Mark in place and have its first cash generating patients before an anticipated next round of funding in 2018. We reiterate our Buy recommendation. Price target is amended to $0.41 following a roll forward of our DCF model.

Absolute Price



SOURCE: IRESS

Earnings Forecast

June Year End	FY16	FY17e	FY18e	FY19e
Revenues	3.8	2.2	5.0	46.3
EBITDA $m	-5.0	-7.4	-10.6	29.4
NPAT (underlying) $m	-4.8	-6.9	-10.1	29.9
NPAT (reported) $m	-4.8	-6.9	-10.1	29.9
EPS underlying (cps)	-1.2	-1.4	-1.9	5.6
EPS growth %	-46%	-17%	-38%	nm
PER (x)	nm	nm	nm	nm
FCF yield (%)	nm	nm	nm	nm
EV/EBITDA (x)	-7.0	-4.7	-3.3	1.2
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	-33.8%	-83.5%	-67.0%	64.3%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Onco Pac 1 Makes Encouraging Progress

The key point from the Onco Pac 1 clinical trial update is as follows:

- **Implant procedure outcomes are consistent with those documented in the prior clinical studies with Oncosil in pancreatic cancer.**

This direct quote from the company's announcement is potentially extremely powerful. The highlights from the previous clinical trials (from a decade ago) include:

- Disease control rate of 82%;
- Average pain reduction of 35%;
- Some patients had grade 3 side Neutropenia (low levels of neutrophils in the blood stream). Note that the neutropenia is associated with the chemotherapy and is unlikely to be caused by Oncosil therapy; and
- Median progression free survival of 121 days (well outside of the 8 week follow up for the 20 patient run in).

The company has not revealed any patient specific data, presumably because there are only 4 patients that have so far received the treatment. Nevertheless, the primary focus of the regulators in Europe at this early stage is clearly safety.

As there are no further safety concerns emerging from these early patients, the outlook for the recruitment of the remaining patients in the 20 patient run in looks very good.

Oncosil has devoted some very significant time and other resources to demonstrating the safety of this **first in class therapy**. We believe the commissioning of new sites and recruitment of patients into the trial has been slower than the company would desire, most likely due to the innovate nature of the procedure and the potential risk this places upon institutions and individual physicians involved with the trial. Understandably some of the clinical sites – particularly in the United States have been slow to obtain all of the necessary approvals.

As the experience base of the product begins to expand, we expect these risks will inevitably dissipate. Onco-Pac 1 is an open label study where the Investigational Device Exemption was the subject of the Pre-Market Approval.

RECRUITMENT UPDATE

Oncosil has now recruited thirteen patients onto the trial and 4 have progressed past the initial chemotherapy to received Oncosil.

12 of the 13 patients have been recruited since the beginning of April 2017 with a further 7 required for the initial 20 patient run in for the CE Mark.

The CE Mark data can take patients from any geography – Australia, the UK or the US. There are now 10 sites able to recruit patients, therefore we expect the remaining 7 to 9 patients (assuming there are 1 or 2 dropouts) within the next few weeks. Patients have a 4 week treatment with chemotherapy followed by treatment with Oncosil. There is an 8 week (i.e. 8 weeks from enrolment) scan which forms the basis of the initial data package.

We estimate the data package for all 20 patient in the initial run in will be completed and ready for submission by 30 September. This should allow ample time for review by the BSI ahead of a CE Mark Approval before year end.

The next update on recruitment will come when the company conducts a quarterly conference call on 8 August.

There are five hospitals recruiting in Australia, three NHS Trusts (in the UK) and two centres in the US. Many of these hospitals are yet to recruit their first patient on the trial,

which again indicates the difficulty in getting started at a particular site, particularly as Oncosil is a first in class therapy.

The company has its own personnel on the ground in the US together with its CRO partners all pushing to accelerate recruitment.

QUARTERLY CASH UPDATE

The operating cash burn for the 3 months to June was $2.37m. OSL raised $950K from shareholders during the period being proceeds from issue of share options.

The company had $8m of cash on hand as at 30 June 2017.

There are no changes to FY18 revenues and costs. Our valuation is amended to $0.41 (from $0.39) following a roll forward of the DCF model. In our view the ongoing recruitment of patients in the trial is highly encouraging and we believe the recruitment rate is set to accelerate as the experience base with the use of Oncosil expands, particularly in the US.

OSL remains likely to be awarded CE Mark approval by year end 2017, and TGA approval in Australia shortly thereafter.

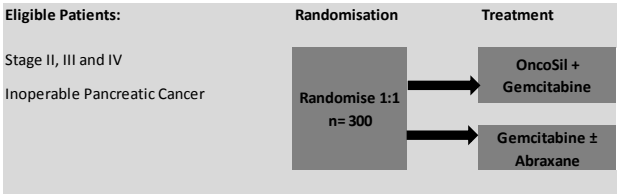
OncoSil Limited

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.

OncoPac-1 is a multicentre, international pivotal study investigating the use of Oncosil for the treatment advanced pancreatic cancer. The US FDA granted an Investigational Device Exemption (IDE) in August 2016.

Figure 1 - Key points from OncoPac-1 trial design



Primary endpoint:	Localised Progression Free Survival
Secondary endpoints:	Overall Survival Progression Free Survival Safety and efficacy Quality of life
Participating countries :	US, Australia, UK, Europe Patients followed until death or 52 week overall survival

SOURCE: BELL POTTER SECURITIES

The trial will include a 20 patient lead in group (all receiving gemcitabine and Oncosil therapy) mainly to study patient safety. The lead in group will have an 8 week follow up period and the company intends to update the market on these outcomes.

KEY RISKS

CE Mark –The CE Mark will allow OSL to commence marketing of OncoSil within the EU. The CE Mark will also serve as a precursor for approvals in other markets including Australia. While the company is confident, that fact is that Oncosil has not been trialled in combination with the current standard of care (Abraxane and Gemcitabine). While the likely risk of rejection is minimal, it remains a risk.

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 OncoPac-1.

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 1 August 2017

Recommendation	Buy
Price	$0.088
Valuation	$0.41

Table 1 - Financial summary

Profit & Loss (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Year Ending June					
Dose sales (units)	-	-	-	120	450
Net revenue from product sales	-	-	-	2.0	3.3
COGS	-	-	-	-0.8	-0.7
Gross profit	-	-	-	1.2	2.6
GP margin	0%	50%	50%	60%	80%
R&D incentive/Upfront receipts	2.8	3.8	2.2	3.0	43.0
Total revenues	**2.8**	**3.8**	**2.2**	**5.0**	**46.3**
Other expenses	**-5.7**	**-8.8**	**-9.6**	**-14.8**	**-16.3**
EBITDA	**-2.9**	**-5.0**	**-7.4**	**-10.6**	**29.4**
Depreciation	0.0	0.0	0.0	0.0	0.0
Amortisation	0.0	0.0	0.0	0.0	0.0
EBIT	-2.9	-5.0	-7.4	-10.6	29.4
Sundry income	0.0	0.3	0.5	0.5	0.5
Pre tax profit	-2.9	-4.8	-6.9	-10.1	29.9
Tax expense	-	-	-	-	-
NPAT- normalised	-2.9	-4.8	-6.9	-10.1	29.9
Net abnormal items	-	-	-	-	-
Reported NPAT	-2.9	-4.8	-6.9	-10.1	29.9

Cashflow (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Gross cashflow	-0.3	-6.4	-4.8	-10.9	29.2
Net interest	0.3	0.3	0.5	0.5	0.5
Tax paid	0.0	0.0	0.0	0.0	0.0
Operating cash flow	-0.1	-4.6	-4.3	-10.4	29.7
Maintenance capex	0.0	-0.1	0.0	0.0	0.0
Capitalised clinical trial spend	0.0	0.0	-1.7	-9.0	-20.0
Free cash flow	-0.1	-4.6	-6.0	-19.5	9.6
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	0.0	11.9	1.0	17.0	0.0
Movement in investments	0.0	0.0	3.3	0.0	0.0
Dividends paid	0.0	0.0	0.0	0.0	0.0
Change in cash held	(0.1)	7.3	(1.8)	(2.5)	9.6
Cash at beginning of period	2.6	2.5	9.8	8.0	5.5
Cash at year end	2.5	9.8	8.0	5.5	15.1

Balance Sheet (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Cash	2.5	9.8	8.0	5.5	15.1
Receivables	0.1	2.6	-	0.3	0.6
Short term investments	3.6	3.3	-	-	-
Other current assets	1.2	0.1	0.1	0.1	0.1
Property, Plant and Equipment	0.1	0.1	0.1	0.2	0.2
Intangible assets	-	-	1.7	10.7	30.7
Total assets	7.4	15.9	10.0	16.9	46.8
Trade payables	0.4	1.0	1.0	1.0	1.0
Other provisions	0.1	0.1	0.1	0.1	0.1
Total Liabilities	0.4	1.1	1.1	1.1	1.1
Net Assets	7.0	14.8	8.9	15.8	45.7
Share capital	23.8	35.7	36.7	53.7	53.7
Retained earnings	(18.7)	(23.5)	(30.4)	(40.5)	(10.6)
Reserves	1.9	2.6	2.6	2.6	2.6
Shareholders Equity	7.0	14.8	8.9	15.8	45.7

Last sale 31/07/2017	0.088
Recommendation	Buy (Spec)
Issued Capital	487.5
Market Cap	42.9

Valuation Ratios (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Reported EPS (cps)	-0.8	-1.2	-1.4	-1.9	5.6
Normalised EPS (cps)	-0.8	-1.2	-1.4	-1.9	5.6
EPS growth (%)	-43%	-46%	-17%	-38%	nm
PE(x)	**nm**	**nm**	**nm**	**nm**	**nm**
EV/EBITDA (x)	-12.0	-7.0	-4.7	-3.3	1.2
EV/EBIT (x)	-12.0	-7.0	-4.7	-3.3	1.2
NTA (cps)	2.0	3.2	1.5	0.9	2.8
P/NTA (x)	0.0	0.0	0.1	0.1	0.0
Book Value (cps)	2.0	3.2	1.8	2.9	8.5
Price/Book (x)	0.0	0.0	0.0	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 %	108%	0%	0%	0%	0%
FCF yield %	-38%	-1510%	-1012%	-2217%	6259%
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)	FY17e	FY18e	FY19e
Europe	-	100	350
USA	-	-	-
Australia/Asia Pacific	-	20	100
Total dose sales	**-**	**120**	**450**

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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