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Oncosil Medical (OSL)

Well Funded, Ready To Rollout

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
$0.113
Valuation
$0.42 (unchanged)
Risk
Speculative

GICS Sector

Healthcare Equipment and Services

Expected Return	
Capital growth	**271%**
Dividend yield	**0.0%**
Total expected return	**271%**
Company Data & Ratios	
Enterprise value	**$70.6m**
Market cap	**$93.6m**
Issued capital	**832.1m**
Free float	**100%**
Avg. daily val. (52wk)	**$336,000**
12 month price range	**$0.05 - $0.21**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.11	0.14	0.07
Absolute (%)	1.99	-19.87	62.59
Rel market (%)	-5.83	-9.26	69.45

Absolute Price

SOURCE: IRESS

Nigel Lange Appointed European President

OSL received the CE Mark for its Oncosil therapy for the treatment of inoperable locally advanced pancreatic cancer in April as anticipated and intends to commence commercialisation of the product later this year.

Following the recent $19m capital raise the company has approximately $23m in cash which is sufficient to provide the working capital for launches in multiple jurisdictions across Europe and Asia Pacific. The funding raising diluted shares on issue by approximately 30%. Based on our assumptions the company has more than 2 years of operating cash, however, these assumption are highly fluid depending mainly upon the rate of uptake by hospitals and the funding requirement of a US approval study.

OSL recently hired Mr Nigel Lange as European, Middle East, Africa President. Mr Lange is a familiar name for many investors and was formerly a senior executive at Sirtex prior to its acquisition. Mr Lange was largely responsible for the growth of SIR Spheres revenues in Europe during the period 2003 – 2018. During this period he established more than 300 centres in the use of the technology. He brings a wealth of knowledge regarding local re-imbursement and numerous hospital contacts in the region. In addition the company has announced an approval in Singapore. This is the first in a series of expected local approvals throughout the Asia Pacific region in the coming months.

The note also includes a brief comparison to SIR Spheres. At the time of launch in Europe in 2004, SIR Spheres had modest data to support a survival benefit and yet it still managed to grow unit sales and revenues every single year up until 2018 when the company was sold for ~A$1.87bn. By comparison Oncosil has the benefit of the meta analysis data which shows a clear survival benefit being approximately double that achieved by the current standard of care in locally advanced pancreatic cancer.

Investment view: Retain Buy (Speculative)

Valuation is unchanged at $0.42 (as we had previously allowed for a capital raise) and we maintain our Speculative Buy recommendation.

Earnings Forecast

June Year End	FY19	FY20e	FY21e	FY22e
Revenues	3.6	3.6	7.2	15.5
EBITDA $m	-8.7	-7.9	-7.5	-11.8
NPAT (underlying) $m	-8.5	-7.7	-7.4	-11.6
NPAT (reported) $m	-8.5	-7.7	-7.4	-11.6
EPS underlying (cps)	-1.4	-1.0	-0.9	-1.4
EPS growth %	nm	-30%	-4%	57%
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%	-39.2%	-60.0%	-1274.6%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Path To First Revenues

Following the awarding of the CE Mark in early April the company will now undertake a measured product launch in Europe – as soon as is practicable following the lifting of visitation restrictions to UK hospitals.

- In the UK (4) and Belgium (1) hospitals which participated in the recent PanCo study remain activated and ready to treat locally advanced pancreatic cancer (LAPC) patients;
- The next 15 hospitals have been identified with discussions under way for the establishment of treatment centres within each. These hospitals are located across the UK, Germany and Belgium.

MARKETING

The company's treatment register is established and will record detailed data on every patient who receives Oncosil therapy including their treatment outcomes and long term survival. The intention is for the register to become the most comprehensive and long term data resource for the treatment of locally advanced pancreatic cancer in the world.

The newly appointed President of EMEA Nigel Lange will be based in Bonn, Germany along with the Global Director of Sales and Marketing Mr Michael Warrener. Both are former executives of Sirtex. As one would expect, these two are fluent German speakers. Mr Lange will have full P&L responsibility for EMEA including business development.

POTENTIAL FOR OFF LABEL USE

The data from the Panco study is impressive. Patients receiving Oncosil therapy achieved median overall survival of 16 months relative to the 8 months under the standard of care. In addition, the safety data and the rate of down staging of border line cases for surgical re-section is impressive.

The rate of down staging for resection in the PanCo study was 24% and is approximately triple the rate in standard of care. Patient's included in the trial were clearly inoperable, and not borderline inoperable cases, hence this statistic is an accurate reflection of the true rate of down staging.

The CE Mark covers only inoperable locally advanced pancreatic cancer. The interpretation of 'in-operable' though is subjective and this is one of the reasons why the register is so important. The data should provide specific information on which types of tumours (position and size) are likely to respond well to treatment. Borderline inoperable cases are a large section of the market and represent up to 10% of the total patient load. We expect that borderline inoperable patients will ultimately be included in the addressable market for LAPC, hence the company's estimates of market size are likely conservative.

COMPARISONS TO SIRTEX

In this section we review the revenue potential of Oncosil with the take up of SIR Spheres from Sirtex. The comparison is of limited value because the two treatments are in difference indications, but nevertheless, the key points are as follows:

- SIR spheres treated liver cancer (both primary and metastatic disease);
- The incidence of liver cancer (for primary and metastatic combined) is within the same ball park as pancreatic cancer. In the US there are a combined 51,000 patients annually and 68,000 in the 5 major markets across Europe;
- SIR spheres never had the benefit of a definitive set of data when Sirtex started commercialisation. In the early years of commercialisation SIR Spheres clinical data was limited to a handful of investigator led studies which only ever showed a

relatively short survival benefit. The predominant use of SIR spheres was in salvage patients who had failed multiple lines of therapy. Despite these limitations sales of SIR spheres grew every single year following launch in 2004;

- Sirtex sold 581 doses of SIR spheres in 2004 (across Europe, USA and Asia Pacific) increasing to ~12,800 doses in 2018. The company was acquired in 2018. The CAGR for unit sales growth over 15 years was ~25% p.a.;
- Conversely Oncosil will be used as a first line therapy supported very high quality meta-analysis from every relevant recent clinical study in the treatment of pancreatic cancer;
- The meta-analysis for Oncosil therapy shows a clear survival benefit. There has not been a significant improvement in the standard of care (being systemic chemotherapy) since 2013.

Despite the absence of data from a large randomised clinical trial to demonstrate a survival benefit, SIR spheres still generated annual dose sales of ~2,700 units in Europe in 2018 representing revenues of ~$38m. Much, if not all of this revenue was from salvage therapy. SIR Spheres also had the benefit of a broad label indication – any inoperable liver cancer regardless of primary or metastatic disease.

We conclude that the availability of Nigel Lange and other executives to run the business in Europe is a material windfall for Oncosil. The Oncosil therapy is far better positioned than SIR spheres ever was to take a commanding market share in the treatment of pancreatic cancer by virtue of its efficacy. With this team of experienced executives now available to drive the establishment of treatment centres across Europe, revenue growth it likely to be accelerated significantly.

ADDRESSABLE MARKET

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

Figure 1 – Total Addressable Market (TAM) Estimate

LAPC	United Kingdom	European Union	United States	Australia	TAM
Estimated Annual Incidence	8,700	79,000	48,000	4,300	
Locally Advanced Pancreatic Cancer Patients @ 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	
FX Rate	0.5093	1.1505	0.637	1.00	
A$m	**68.3**	**412.0**	**941.9**	**43.0**	**1,465**

SOURCE: BELL POTTER SECURITIES ESTIMATES

The inclusion of the borderline resection market adds ~$300K to the BP estimate of annual addressable market. Other off label treatment groups are those with bile duct cancer (which is the subject of humanitarian device exemption) in the US.

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. We have not included revenue from a partnering deal in the forecast.

VALUATION

There are no changes to earnings. Our previous valuation had incorporated EPS dilution from a likely capital raise. We retain our valuation of $0.42

Following the $19m capital raise OSL now has ~$23m in cash. In the short term, the cash burn rate is likely to remain low and in line with recent quarters (i.e. ~$2m) up until the product is launched in Europe.

Based on our forecast the company has sufficient capital 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 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 4 June 2020

Recommendation	Buy, Speculative
Price	$0.113
Valuation	$0.42

Table 1 - Financial summary

Profit & Loss (A$m)	FY18	FY19	FY20e	FY21e	FY22e
Year Ending June					
Dose sales (units)	-	-	-	175	490
Net revenue from product sales	-	-	0.6	4.2	10.5
COGS	-	-	- 0.1	-0.8	-2.1
Gross profit	-	-	0.5	3.4	8.4
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**	**7.2**	**15.5**
Other expenses	**-5.8**	**-5.6**	**-4.0**	**-2.0**	**-12.0**
Other expenses	**-13.1**	**-6.7**	**-7.3**	**-11.9**	**-13.2**
EBITDA	**-8.7**	**-8.7**	**-7.9**	**-7.5**	**-11.8**
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	-7.5	-11.7
Sundry income	0.2	0.2	0.1	0.1	0.1
Pre tax profit	-8.6	-8.5	-7.7	-7.4	-11.6
Tax expense	-	-	-	-	-
NPAT- normalised	-8.6	-8.5	-7.7	-7.4	-11.6
Net abnormal items	-	-	-	-	-
Reported NPAT	-8.6	-8.5	-7.7	-7.4	-11.6

Cashflow (A$m)	FY18	FY19	FY20e	FY21e	FY22e
Gross cashflow	-8.5	-7.7	-7.0	-4.8	-12.3
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	-4.7	-12.2
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	-4.8	-12.3
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	15.6	0.0	17.1	0.0	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)	10.1	(4.8)	(12.3)
Cash at beginning of period	8.0	15.2	7.7	17.8	13.0
Cash at year end	15.2	7.7	17.8	13.0	0.7

Balance Sheet (A$m)	FY18	FY19	FY20e	FY21e	FY22e
Cash	15.2	7.7	17.8	13.0	0.7
Receivables	4.5	3.8	3.0	0.3	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	21.0	13.6	1.9
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	20.0	12.6	0.9
Share capital	52.3	52.3	69.3	69.3	69.3
Retained earnings	(39.1)	(47.6)	(55.3)	(62.8)	(74.4)
Reserves	5.0	6.0	6.0	6.0	6.0
Shareholders Equity	18.2	10.7	20.0	12.6	0.9

Last sale 04/06/2020	0.113
Recommendation	Buy (Spec)
Issued Capital	832.1
Market Cap	93.6

Valuation Ratios (A$m)	FY18	FY19	FY20e	FY21e	FY22e
Reported EPS (cps)	-1.7	-1.4	-1.0	-0.9	-1.4
Normalised EPS (cps)	-1.7	-1.4	-1.0	-0.9	-1.4
EPS growth (%)	-11%	nm	-30%	-4%	0.6
PE(x)	**nm**	**nm**	**nm**	**nm**	**nm**
EV/EBITDA (x)	-8.1	nm	nm	nm	nm
EV/EBIT (x)	-8.1	nm	nm	nm	nm
NTA (cps)	2.9	1.7	2.5	1.5	0.1
P/NTA (x)	0.0	0.1	0.0	0.1	1.0
Book Value (cps)	2.9	1.7	2.5	1.5	0.1
Price/Book (x)	0.0	0.1	0.0	0.1	1.0
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 %	-1202%	-1075%	-756%	-521%	-1342%
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	-	-	90
Total dose sales	**-**	**175**	**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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