BELL POTTER

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Speculative
Refer to key risks on pages 5, 6 and 8. Speculative securities may not be suitable for retail clients

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Oncosil Medical (OSL)

One Giant Step for OncoSil

Recommendation
Buy (unchanged)
Price
$0.165
Valuation
$0.33 (previously $0.30)
Risk
Speculative

GICS Sector

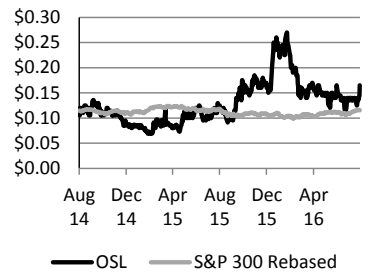
Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	**100%**
Dividend yield	**0%**
Total expected return	**100%**
Company Data & Ratios	
Enterprise value	**$63.3m**
Market cap	**$76.6m**
Issued capital	**464.5m**
Free float	**100%**
Avg. daily val. (52wk)	**$329,000**
12 month price range	**$0.08 - $0.275**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.13	0.15	0.12
Absolute (%)	32.00	13.79	43.48
Rel market (%)	24.20	6.84	44.47

Absolute Price



SOURCE: IRESS

Commercial Revenues Closer

Earlier today OncoSil announced that it had received an Investigational Device Exemption (IDE) from the US FDA. The company will now initiate a pivotal clinical trial for OncoSil for the treatment of inoperable pancreatic cancer.

The first patient in this 300 patient study is expected to be enrolled in early 2017. The primary endpoint is localised progression free survival. The secondary endpoints include progression free survival and overall survival. As per our previous research on the likely trial design, the FDA's acceptance of the localised progression free survival primary endpoint is a significant boost to the prospects of success in this trial.

The randomised study will compare OncoSil+Chemotherapy to chemotherapy alone. In earlier studies (conducted nearly a decade ago) the vast majority of patients (83%) showed a response to the treatment, hence the decision by the FDA to approve the study in this first in class treatment for the disease is exciting news.

This open label study will report regularly beginning with the first cohort of 20 patients where the FDA will focus primarily on safety. Following this, we expect a significant acceleration in recruitment due to the absence of competing clinical trials.

OSL had $13.3m in cash at 30 June 2016 which we believe is ample to commence the trial. We expect the cost of the pivotal clinical trial to be in the range of US$24m – US$26m over the next two to three years.

Maintain Buy Recommendation, Valuation raised to $0.33

The awarding of the IDE is a major step forward for this first in class therapy, consequently the valuation is raised by 10% to $0.33. Overall changes to earnings in the forecast period are not material in absolute terms. We maintain our Buy recommendation.

Earnings Forecast

June Year End	FY15	FY16e	FY17e	FY18e
Revenues	2.8	2.5	3.5	5.1
EBITDA $m	-2.9	-5.3	-6.1	-10.5
NPAT (underlying) $m	-2.9	-4.8	-5.6	-10.0
NPAT (reported) $m	-2.9	-4.8	-5.6	-10.0
EPS underlying (cps)	-0.8	-1.2	-1.2	-1.9
EPS growth %	-43%	47%	-1%	66%
PER (x)	-0.2	-0.1	-0.1	-0.1
FCF yield (%)	-20%	-634%	-788%	-1185%
EV/EBITDA (x)	-21.9	-12.0	-10.4	-6.1
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	-41.6%	-37.4%	-71.9%	-66.9%

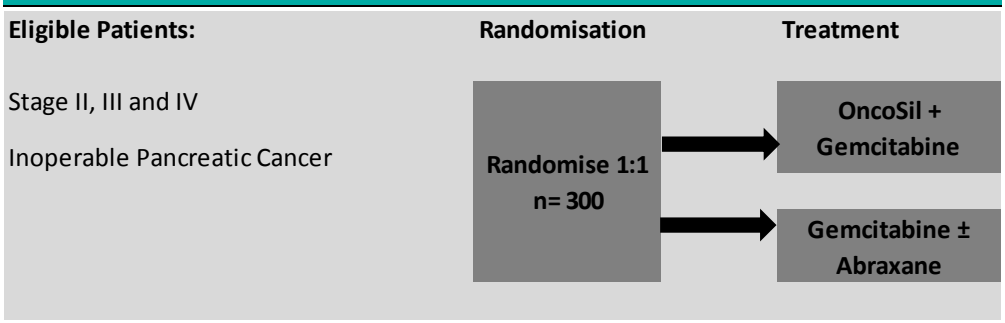
SOURCE: BELL POTTER SECURITIES ESTIMATES

Overview of the clinical study design

The pivotal study will be known as OncoPac-1.

The granting of the Investigational Device Exemption (IDE) by the FDA in the United States follows an extensive preparatory period and 8 months of negotiations mainly associated with safety. 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.

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

We estimate cost per patient at ~US$85,000, hence the cost of this trial is estimated at between US$24m – US$26m.

Localised progression free survival is a logical primary endpoint given this is the first significant study of its nature in the US. A successful outcome (such as 50% of patients achieving at least 30% reduction in tumour volume) is likely to attract the attention of oncologists.

There is no comparable data for LPFS, but we do expect OncoSil therapy to be highly effective at controlling the disease within the pancreas.

OncoSil is a localised therapy being combined with two chemotherapy agents (systemic agents). Median PFS (i.e. progress of the disease either within the pancreas or at any other site) is currently 121 days (based on the earlier pilot study).

We are surprised to see progression free survival included as a secondary endpoint. The asymptomatic nature of pancreatic cancer typically results in late diagnosis and therefore most patients on the trial are likely to have extensive metastases. While the chemotherapy may control these metastases, Oncosil will have no impact.

The secondary endpoint of overall survival is also logical. Overall survival remains the benchmark for FDA approval, however in this case the FDA has agreed to the primary endpoint of localised progression free survival presumably because patients with advanced pancreatic cancer face such bleak prospects with long term survival rates very low. Controlling the growth of the primary tumour(s) is the priority.

Pain management is also a worthy secondary objective. The earlier clinical trials of OncoSil demonstrated that reductions in pancreatic tumour burden were associated with meaningful reductions in pain levels. This measure is likely to contribute to quality of life considerations.

Regulatory Pathway

The company has been careful not to discuss an approval pathway that may be associated with outcomes from this trial. OSL previously disclosed that its application for the IDE was accompanied by a premarket approval (PMA). The first step to gaining the PMA is the clinical evidence from a randomised trial. Clinically significant results from OncoPac-1 may lead to marketing approval in the US without the need for a further study. We expect the company will have more to say about its regulatory pathway as results emerge from this study over the next couple of years.

There is no discussion at this time regarding whether the trial is powered for statistical significance or the expected extension in survival rates.

Short Term Catalysts

As with any new device trial, support from clinicians is critical. We expect recruitment in the trial will be led by Dr. Joseph Herman from Johns Hopkins University. Dr Herman is on the Clinical Advisory Board for OSL.

As OncoSil has a relatively benign side effect profile with the potential for meaningful extension in overall survival and no competing clinical trials, the prospects for fast recruitment are promising. Once the initial cohort of 20 patients is recruited and assessed for safety, recruitment will be extended to include up to 30 centres in the US, Australia, UK and Europe.

Valuation

The 300 patient study is larger than the 250 patients we had anticipated for OncoPac-1, hence we have increased the cost of the trial in FY19. We have increased the size of the subsequent capital raising expected in FY18 from $13.0m to $17.0m reflecting this cost. We capitalise the entire cost of the clinical trial.

We have also amended FY16 revenues to reflect no revenues from dose sales and we amend FY17 revenues to reflect the delay in CE mark approval.

The closing cash balance at 30 June 2016 is also amended to reflect the recent cash flow statement. Overall changes to earnings are not material in absolute terms.

Figure 2 - Summary of earnings changes

	2016			2017			2018		
	New	Old	% change	New	Old	% change	New	Old	% change
Revenues	2.5	2.6	-4%	3.5	3.9	-10%	5.1	5.1	1%
EBITDA	-5.3	-6.3	16%	-6.1	-7.6	19%	-10.5	-10.5	0%
NPAT	-4.8	-5.8	17%	-5.6	-7.1	21%	-10.0	-10	0%
EPS's	-1.2	-1.4	16%	-1.2	-1.6	27%	-1.9	-2.1	8%

SOURCE: BELL POTTER SECURITIES

Figure 3 - DCF Summary

DCF Valuation - Firm Value $million	($1000,000)
Total PV of Explicit Free Cashflow	28.5
Total PV of Continuing Year	128.7
Enterprise Value	157.1
Less Net Debt	-13.0
Equity Value	170.1
Number of Shares (million)	514.0
Equity Value Per Share	$0.33
Dividends prior to valuation base date yet to be received	$0.00
Net cashflow valuation per share incl cum dividends	$0.33
Franking Credits per share (valued at 30¢ in the $)	$0.00
Total Value Per Share	$0.33

SOURCE: BELL POTTER SECURITIES

Shares on issue in figure 3 reflects the full dilution expected following a subsequent capital raising.

Despite the earnings changes and additional capital raising, the key change in the DCF is the prospective cost of capital. The overall cost of capital is amended downward by approximately 100bps to 13.8% following the award of the IDE which in our view should lower the risk profile. Following these changes and a roll forward of the model to FY17, target price is raised by $0.03 to $0.33.

OncoSil

OncoSil Medical is a medical device company whose key asset is the global rights to the brachytherapy treatment known as OncoSil™. The product has been developed under an exclusive world-wide licence from pSiMedica.

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 85,000 new 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.

The standard of care for pancreatic cancer was recently amended and is now a combination of two chemotherapy drugs Abraxane and Gemcitabine. In the phase III study which led to the addition of Abraxane to standard of care for the treatment of late stage patients, median overall survival was 8.5 months. In contrast, a 17 patient pilot study of OncoSil combined with Gemcitabine in a similar patient group produced a median overall survival of 10 months.

OncoSil has an outstanding safety profile. In the pilot study there were no serious adverse events associated with the treatment. OnsoSil is dosed via an endoscope and normally requires only light anaesthetic. Patients are normally discharged on the same day.

OncoSil has been granted an Investigational Device Exemption (IDE) and will commence a pivotal study in early 2017. We expect the company to take advantage of the recently created Expedited Access Pathway and this may see first commercial revenues in the USA as early as 2019.

Subject to the final CE Mark approval, in our view all the key elements to drive first commercial revenues are now in place. The awarding of the CE mark will be the catalyst to drive this next phase. We expect OncoSil will derive annual revenues of at least $20m within 5 years.

Based on the high unmet need and absence of any emerging alternative therapy, the potential for accelerating revenues once critical mass is established appears strong.

KEY RISK AREAS

CE Mark – OSL has now been waiting more than 1 year for CE mark approval which would allow it 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 – 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 results 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 will rely on significant patient funding in Europe – at least initially. We do not expect OncoSil will attract significant funding from payers in Europe and the UK. In the US, payers are likely to support the cost of the treatment provided it is proved safe with suitable efficacy throughout the clinical trial process.

Financial Risk – The cost of the OncoPac-1 is estimated at between US$20m - US$25m. As at 30 June 2016 OSL had approximately $13m in cash. It is unlikely this will be sufficient to fund the entire clinical program and commercial roll out of OncoSil in Europe. Notwithstanding, initial success in commercial sales and the clinic is likely to be well received by investors and this may attract further capital and potentially better than expected revenues.

Clinical Risk – 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 2 August 2016

Recommendation	Buy, Speculative
Price	$0.165
Valuation	$0.33

Table 1 - Financial summary

Profit & Loss (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Year Ending June					
Dose sales (units)	-	-	70	140	800
Net revenue from product sales	-	-	0.5	2.1	7.2
COGS	-	-	0.4	-0.9	-1.4
Gross profit	-	-	0.3	1.3	5.8
GP margin	0%	50%	50%	60%	80%
R&D incentive/Upfront receipts	2.8	2.5	3.0	3.0	43.0
Total revenues	**2.8**	**2.5**	**3.5**	**5.1**	**50.2**
Other expenses	**-5.7**	**-7.8**	**-9.4**	**-14.7**	**-17.2**
EBITDA	**-2.9**	**-5.3**	**-6.1**	**-10.5**	**31.5**
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	-5.3	-6.1	-10.5	31.5
Sundry income	0.0	0.5	0.5	0.5	0.5
Pre tax profit	-2.9	-4.8	-5.6	-10.0	32.0
Tax expense	-	-	-	-	-
NPAT- normalised	-2.9	-4.8	-5.6	-10.0	32.0
Net abnormal items	-	-	-	-	-
Reported NPAT	-2.9	-4.8	-5.6	-10.0	32.0

Cashflow (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Gross cashflow	-0.3	-5.3	-6.5	-10.5	30.8
Net interest	0.3	0.5	0.5	0.5	0.5
Tax paid	0.0	0.0	0.0	0.0	0.0
Operating cash flow	-0.1	-4.8	-6.0	-10.0	31.3
Maintenance capex	0.0	0.0	0.0	0.0	0.0
Capitalised clinical trial spend	0.0	0.0	-2.3	-9.0	-22.6
Free cash flow	-0.1	-4.9	-8.3	-19.1	8.6
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	0.0	12.0	0.0	17.0	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	(0.1)	7.2	(8.3)	(2.1)	8.6
Cash at beginning of period	6.2	6.1	13.3	5.0	2.9
Cash at year end	6.1	13.3	5.0	2.9	11.6

Balance Sheet (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Cash	6.1	13.3	5.0	2.9	11.6
Receivables	0.1	0.1	0.1	0.4	1.2
Short term investments	-	-	-	-	-
Other current assets	1.2	1.2	1.5	1.5	1.5
Property, Plant and Equipment	0.1	0.1	0.1	0.2	0.2
Intangible assets	-	-	2.3	11.3	33.9
Total assets	7.4	14.6	9.0	16.2	48.4
Trade payables	0.4	0.4	0.4	0.5	0.7
Other liabilities	-	-	-	-	-
Debt - interest bearing debt	0.1	0.1	0.1	0.1	0.1
Total Liabilities	0.4	0.4	0.5	0.6	0.8
Net Assets	7.0	14.2	8.5	15.6	47.7
Share capital	23.8	35.8	35.8	52.9	52.9
Retained earnings	(18.7)	(23.5)	(29.2)	(39.1)	(7.1)
Reserves	1.9	1.9	1.9	1.9	1.9
Shareholders Equity	7.0	14.2	8.5	15.6	47.7

Last sale 02/08/2016	0.165
Recommendation	Buy (Spec)
Issued Capital	464.5
Market Cap	76.6

Valuation Ratios (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Reported EPS (cps)	-0.8	-1.2	-1.2	-1.9	6.2
Normalised EPS (cps)	-0.8	-1.2	-1.2	-1.9	6.2
EPS growth (%)					
PE(x)	**-0.2**	**-0.1**	**-0.1**	**-0.1**	**0.0**
EV/EBITDA (x)	-21.9	-12.0	-10.4	-6.1	2.0
EV/EBIT (x)	-22.0	-12.0	-10.4	-6.1	2.0
NTA (cps)	2.0	3.1	1.4	0.8	2.7
P/NTA (x)	0.1	0.1	0.1	0.2	0.1
Book Value (cps)	2.0	3.1	1.8	3.0	9.3
Price/Book (x)	0.1	0.1	0.1	0.1	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 %	-20%	-634%	-788%	-1185%	3682%
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	50	100	560
USA	-	-	140
Australia/Asia Pacific	20	40	100
Total dose sales	**70**	**140**	**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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