ONCOSIL MEDICAL (OSL)

Wilson HTM EQUITIES RESEARCH

BUY | HOLD | SELL

Company update

IDE submission for OncoSil

Oncosil Medical has made its first submission to the FDA, seeking approval to trial its brachytherapy device for the treatment of pancreatic cancer. A well-designed, pivotal clinical trial is required to support a future application to market the product in the US. Later this quarter, the FDA's response letter and further trial design detail should come to light, clarifying the pathway towards US licensure. Meanwhile, the European approval process has encountered a longer review period than expected, but we remain confident. We maintain a SPECULATIVE BUY rating. Target price upgraded to 50 cps (risked) with potential, milestone-dependent upside to $1/share over the next 12 months.

Key points

Oncosil has filed an application with the FDA to conduct a new clinical trial of OncoSil™ in the treatment of pancreatic cancer – this IDE filing sets out Oncosil's investigational plan to test the safety and efficacy of OncoSil™ in a study which may ultimately support marketing approval in the US.

FDA response letter is the next catalyst – FDA review times can be as short as 30 days for IDE applications, so a positive outcome could see Oncosil's trial recruiting patients by the second quarter. IDE approvals give no assurances with respect to the future approval of products, but they do confirm that the agency sees a reasonable case that the product's putative benefits outweigh the safety risks faced by patients participating in the trial.

The FDA's response letter and the release of Oncosil's proposed trial design are the next catalysts which will help characterise the costs, timing and likelihood of its first US approval. We are anticipating a 225-275 patient study to examine surrogate endpoints such as local progression free survival and tumour regression (overall response rates).

CE Mark process ongoing – the European approval process has taken longer than the company anticipated. The value of the CE Marking process, from our perspective, is independent validation of Oncosil's systems/technologies.

Valuation – our risked DCF lifts to 50 cps in anticipation of FDA clearance and increased confidence in development plans. Un-risked valuation for Oncosil suggests further potential of up to $2.75 per share over a 3-5 year period (upside case) on a fully diluted basis.

Risks and catalysts

Catalysts: a) CE Mark; b) FDA trial guidance; c) EU marketing approval and first sales. **Risks**: a) access to capital; b) clinical trial design risk; c) regulatory risks; d) product safety/quality/logistics risks; e) sector sentiment.

12-mth target price (AUD)	**$0.50**
Share price @ 21-Jan-16 (AUD)	$0.26
Forecast 12-mth capital return	96.2%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	**96.2%**
Market cap	$94m
Enterprise value	$75m
Shares on issue	368m
Sold short	0.2%
ASX 300 weight	n/a
Median turnover/day	$0.2m

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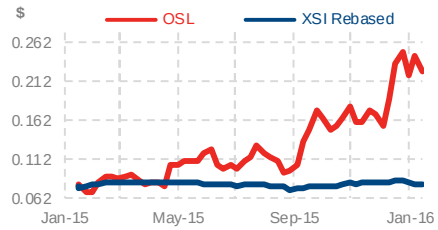
12-mth share price performance



	1-mth	6-mth	12-mth
Abs return (%)	-2.2	87.5	196.1
Rel return (%)	2.6	89.0	192.6

Year-end June (AUD)	FY14A	FY15A	FY16F	FY17F	FY18F
NPAT rep ($m)	-4.2	-2.9	-6.1	-9.9	-8.5
NPAT norm ($m)	-4.2	-2.9	-6.1	-9.9	-8.5
Consensus NPAT ($m)			-6.1	-9.9	-8.6
EPS norm (cps)	-1.4	-0.8	-1.6	-2.2	-1.9
EPS growth (%)	-139.6	40.4	-97.4	-35.4	13.4
P/E norm (x)	-18.7	-31.5	-15.9	-11.8	-13.6
EV/EBITDA (x)	-16.0	-25.0	-12.3	-7.5	-8.8
FCF yield (%)	-6.8	-0.2	-6.8	-11.6	1.5
DPS (cps)	0.0	0.0	0.0	0.0	0.0
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0
Franking (%)	0	0	0	0	0

Source: Company data, WHTM estimates, S&P Capital IQ

KEY CHANGES		17-Nov	After	Var %
NPAT:	**FY16F**	-6.1	-6.1	0.0%
norm	**FY17F**	-9.9	-9.9	0.0%
($m)	**FY18F**	-8.5	-8.5	0.0%
EPS:	**FY16F**	-1.6	-1.6	0.0%
norm	**FY17F**	-2.2	-2.2	0.0%
(cps)	**FY18F**	-1.9	-1.9	0.0%
DPS:	**FY16F**	0.0	0.0	0.0%
(cps)	**FY17F**	0.0	0.0	0.0%
	FY18F	0.0	0.0	0.0%
Price target:		0.35	0.50	43.9%
Rating:		**BUY**	**BUY**	

PRICE TARGET

	Valuation	Price target
WACC (%)	14	
Tg (%)	4	
NPV fcst FCF	54	
NPV perpetuity	139	
Net debt/(cash)	-5	
Valuation ($m)	197	
DCF ($/share)		0.39
HCC option ($/share)		0.11
Price target ($ /share)		**0.50**
Un-risked 3-yr valuation		**2.75**

INTERIMS ($m)

Half-year (AUD)	Dec 14 1HA	Jun 15 2HA	Dec 15 1HE	Jun 16 2HE
Sales revenue	0.0	0.0	0.7	0.8
EBITDA	-2.5	-0.6	-1.7	-4.4
EBIT	-2.5	-0.6	-1.7	-4.4
Net profit	**-2.5**	**-0.4**	**-1.7**	**-4.4**
Norm EPS	**-0.7**	**-0.1**	**-0.5**	**-1.1**
EBIT/sales (%)			-256.1	-586.9
Dividend (c)	0.0	0.0	0.0	0.0
Franking (%)	0.0	0.0	0.0	0.0

FINANCIAL STABILITY

Year-end June (AUD)	FY15A	FY16F	FY17F
Net debt	-2.5	-18.4	-7.5
Net debt/equity (%)	<0	<0	<0
Net debt/EV (%)	**<0**	**<0**	**<0**
Current ratio (x)	16.6	33.0	14.8
Interest cover (x)	19.9	78.5	33.1
Adj cash int cover (x)	**2.4**	**82.7**	**36.4**
Debt/cash flow (x)	0.0	0.0	0.0
Net debt (cash)/share ($)	<0	<0	<0
NTA/share ($)	0.0	0.1	0.0
Book value/share ($)	0.0	0.0	0.0
Payout ratio (%)	0	0	0
Adj payout ratio (%)	0	0	0

EPS RECONCILIATION ($m)

	FY15A		FY16F	
	Rep	Norm	Rep	Norm
Sales revenue	0	0	1	1
EBIT	-3.0	-3.0	-6.2	-6.2
Net profit	**-2.9**	**-2.9**	**-6.1**	**-6.1**
Notional earn	0.0	0.0	0.0	0.0
Pref/conv div	0.0	0.0	0.0	0.0
Profit for EPS	**-2.9**	**-2.9**	**-6.1**	**-6.1**
Diluted shrs (m)	355	355	380	380
Diluted EPS (c)	**-0.8**	**-0.8**	**-1.6**	**-1.6**

RETURNS

	FY15A	FY16F	FY17F	FY18F
ROE (%)	-30.1	-48.0	-73.3	-201.1
ROIC (%)	-30.6	-193.6	-1,352.6	154.3
Incremental ROE	293.8	-103.1	-486.0	-14.4
Incremental ROIC	125.0	46.6	164.8	-23.9

KEY ASSUMPTIONS

Year-end June (AUD)	FY13A	FY14A	FY15A	FY16F	FY17F	FY18F	FY19F	FY20F
Revenue growth (%)	-100.0				41.4	54.0	228.2	50.0
EBIT growth (%)	-104.9	382.6	-35.9	103.3	65.0	-14.9	-38.8	-121.9
NPAT growth (%)	-105.1	379.7	-31.7	111.3	62.1	-13.4	-39.7	-123.6
EPS growth (%)	**-101.9**	**139.6**	**-40.4**	**97.4**	**35.4**	**-13.4**	**-39.7**	**-123.6**
EBIT/sales (%)				-431.4	-503.5	-278.1	-51.9	7.6
Tax rate (%)	0.0	6.9	0.0	0.0	0.0	0.0	0.0	0.0
ROA (%)	**-15.7**	**-38.5**	**-40.9**	**-50.2**	**-118.5**	**-106.1**	**-76.3**	**14.8**
ROE (%)	**-14.5**	**-34.7**	**-41.4**	**-59.4**	**-180.7**	**366.7**	**164.9**	**-62.1**

PROFIT AND LOSS ($m)

Year-end June (AUD)	FY13A	FY14A	FY15A	FY16F	FY17F	FY18F	FY19F	FY20F
Sales revenue	0.0	0.0	0.0	1.4	2.0	3.1	10.2	15.3
EBITDA	-1.0	-4.7	-3.0	-6.1	-10.1	-8.6	-5.2	1.2
Depn & amort	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.1
EBIT	**-1.0**	**-4.7**	**-3.0**	**-6.2**	**-10.2**	**-8.7**	**-5.3**	**1.2**
Net interest expense	-0.1	-0.2	-0.2	-0.1	-0.3	-0.1	-0.1	-0.1
Tax	0.0	-0.3	0.0	0.0	0.0	0.0	0.0	0.0
Minorities/pref divs	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Equity accounted NPAT	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net profit (pre-sig items)	**-0.9**	**-4.2**	**-2.9**	**-6.1**	**-9.9**	**-8.5**	**-5.2**	**1.2**
Abns/exts/signif	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Reported net profit	**-0.9**	**-4.2**	**-2.9**	**-6.1**	**-9.9**	**-8.5**	**-5.2**	**1.2**

CASH FLOW ($m)

Year-end June (AUD)	FY13A	FY14A	FY15A	FY16F	FY17F	FY18F	FY19F	FY20F
EBITDA	-1.0	-4.7	-3.0	-6.1	-10.1	-8.6	-5.2	1.2
Interest & tax	-0.1	-0.2	2.8	-0.1	-0.3	-0.1	-0.1	-0.1
Working cap/other	0.6	-1.4	0.1	0.2	-0.2	10.3	-0.3	-0.4
Operating cash flow	**-0.5**	**-6.4**	**-0.2**	**-6.0**	**-10.7**	**1.6**	**-5.7**	**0.8**
Maintenance capex	0.0	0.0	0.0	-0.4	-0.2	-0.2	-0.2	-0.2
Free cash flow	**-0.5**	**-6.4**	**-0.2**	**-6.4**	**-10.9**	**1.4**	**-5.9**	**0.6**
Dividends paid	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Growth capex	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Invest/disposals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other inv flows	-0.2	-4.7	0.0	0.0	0.0	0.0	0.0	0.0
Cash flow pre-financing	**-0.7**	**-11.1**	**-0.2**	**-6.4**	**-10.9**	**1.4**	**-5.9**	**0.6**
Funded by equity	1.8	10.3	0.0	17.5	0.0	0.0	0.0	0.0
Funded by debt	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Funded by cash	-1.1	0.8	0.2	-11.1	10.9	-1.4	5.9	-0.6

BALANCE SHEET SUMMARY ($m)

Year-end June (AUD)	FY13A	FY14A	FY15A	FY16F	FY17F	FY18F	FY19F	FY20F
Cash	3.5	2.7	2.5	18.4	7.5	8.9	3.0	3.5
Current receivables	0.0	0.1	0.1	0.2	1.0	1.0	2.2	3.1
Current inventories	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.2
Net PPE	0.0	0.0	0.1	0.4	0.6	0.7	0.9	1.0
Investments	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Intangibles/capitalised	2.6	2.6	0.0	0.0	0.0	0.0	0.0	0.0
Other	0.0	6.7	4.8	0.0	0.0	0.0	0.0	0.0
Total assets	**6.2**	**12.3**	**7.4**	**18.9**	**9.1**	**10.6**	**6.2**	**7.8**
Current payables	0.1	0.0	0.2	0.3	0.3	0.4	1.1	1.5
Total debt	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other liabilities	0.1	0.1	0.3	0.3	0.3	10.3	9.3	8.3
Total liabilities	**0.2**	**0.1**	**0.4**	**0.6**	**0.6**	**10.7**	**10.3**	**9.8**
Minorities/convertibles	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Shareholder equity	**6.1**	**12.2**	**7.0**	**18.4**	**8.5**	**0.0**	**-4.2**	**-2.0**
Total funds employed	**6.1**	**12.2**	**7.0**	**18.4**	**8.5**	**0.0**	**-4.2**	**-2.0**

Oncosil Medical submits IDE application to the FDA

OncoSil™'s FDA regulatory pathway commences

OncoSil™ IDE submission – Oncosil has applied for FDA clearance to deploy its product OncoSil™ in a clinical trial involving clinical centres in the US. The trial will be a global one, but this specific FDA approval is required for US clinical sites and subjects to be involved. We understand that the company has been in dialogue with the FDA for several months, seeking commentary and guidance in relation to clinical trial designs that can potentially support an FDA approval for OncoSil™. The FDA will now scrutinise Oncosil's Investigational Device Exemption (IDE) application via a formal review process that can take as little as 30 days[1]. We expect the trial will commence this year, if the IDE is approved shortly (with or without conditions).

A successful IDE application would allow Oncosil to commence a clinical trial to test its product in the US

Importantly, an IDE trial approval offers no guarantees – when the FDA reviews IDE applications, its primary focus is to determine whether the risks to the patient are outweighed by the anticipated clinical benefits. While pre-IDE meetings and other correspondence with the FDA set out the agency's current thinking on matters influencing future marketing approval, an IDE approval does not pre-empt or inform subsequent reviews of the product's safety and efficacy. Final marketing approval for OncoSil™ may come via a Pre-Market Approval (PMA) application, which requires at least one well-designed pivotal clinical study showing a clinically meaningful benefit. IDE trials often form the centrepiece of PMAs.

In approving an IDE trial, the FDA is not bound to accept or approve the product on the basis of that trial

IDE trial protocol will allow investors to estimate the costs, timing and likelihood of a first US approval – several controversies remain in relation to Oncosil's planned pivotal study. Oncosil has argued that "surrogate" endpoints such as local progression free survival (PFS[2]) and/or tumour response ought to be pursued, instead of overall survival (OS) as a primary endpoint. Although OS is clearly the superior endpoint for cancer trials, it can be expensive and time consuming to measure, delaying patient access to new products for years. Most cancer drugs obtain their first FDA approvals on the basis of surrogate endpoints, rigorously examined by well-designed, albeit smaller, clinical trials. The FDA has clear procedures for considering and approving new cancer products via "accelerated review" on the basis of surrogate endpoints. In April 2015, this approval pathway was opened up for medical devices, for the first time. OncoSil™ may qualify for this form of expedited review and approval if their trial data proves to be supportive.

In our view, an IDE trial measuring surrogate endpoints could support a first FDA approval

IDE trial design considerations revisited:

- **Clinical endpoints likely to be local PFS and/or tumour regression measured as an overall response rate (ORR[3])** – the ability to control or better, shrink, primary pancreatic tumours is the number one problem that pancreatic medical oncologists and patients face. Even after the point of metastasis, when the tumour has spread to other organs, the primary pancreatic tumour remains both lethal and the principal cause of intractable, severe pain. Local tumour control would be a clinically persuasive result for OncoSil™.

Local PFS and ORR endpoints are well characterised in the pancreatic cancer setting

- **Secondary endpoints usually selected with clinical adoption and reimbursement outcomes in mind** – Oncosil's early studies showed interesting trends towards durable responses and overall survival (see Table 1). Oncosil may include OS as a secondary endpoint, as well as other characteristics like pain relief.

- **What therapy should OncoSil™ be compared to?** The IDE trial should have two basic arms: gemcitabine/ABRAXANE plus OncoSil™ versus gemcitabine/ABRAXANE alone. That would constitute a highly relevant trial for the US market, where the gemcitabine/ABRAXANE chemotherapy combination is in the process of becoming standard of care.

OncoSil™ should be tested head to head against the current "standard of care"

[1] FDA recently reported reductions in their review periods for investigational devices – from an average of 442 days in 2011 to just 30 days in 2015. The FDA said that the percentage of IDE submissions approved within 2 Q&A cycles increased from 15% in 2011 to 72% in 2015.
[2] PFS is the length of time during and after treatment, that a patient lives with the disease but it does not get worse. In a clinical trial, measuring the *PFS* is one way to see how well the new treatment works.
[3] The FDA defines ORR as the "proportion of patients with a tumor size reduction of a predefined amount and for a minimum period of time".

- **Expecting a 225-275 patient trial size** – at this stage, the size of pivotal trial required to establish the desired endpoints is a guess, because the indicative effect size of adding adjuvant OncoSil™ alongside gemcitabine/ABRAXANE chemotherapy is unknown. Our initial estimate of 225-275 patients (randomised 1:1) was based on OncoSil™ improving an ORR by 100% – in the context of a pivotal study. Our calculation also assumed a 20% ORR for patients treated with gemcitabine/ABRAXANE[4] and a 40% response rate for those patients receiving OncoSil™ in combination.

  In completed Phase I/II studies, OncoSil™ has achieved ORRs[5] as high as 50% or as low as 13% – but both studies were small and were not designed to say anything comparative about the product in relation to background chemotherapy.

We estimate a trial size of 225-275 patients would be required to reach endpoints with statistical significance

Table 1: Early OncoSil™ studies have demonstrated anti-tumoural activity worth exploring further in randomised clinical trials

Study	Design	Dose	n	Results	Adverse Events
BIOSP-201 (2005)	Single dose, single centre open label safety study in **hepatocellular carcinom**a (HCC)	4 MBq/mL of tumour. Up to 60MBq per lesion or up to 180 MBq per patient.	8 patients (of w hich 5 completed the study) all of Asian race.	Complete response - 25% Partial response - 25% Stable disease - 38% Disease progression - 13% **All** tumours shrank by 16-100%. Durable responses in 50% patients out to 24 w eeks post treatment.	No Grade 3 or 4 toxicities related to OncoSil™.
BIOSP-202 (2006)	Multi-centre, dose escalating study in **HCC**		11 patients (1 w ithdraw al). Terminated due to poor recruitment. All patients of Asian race.		
DB2-201	Multi-centre, open label study in locally advanced **pancreatic cancer**	100 Gy (6.4 MBq/mL)	17 patients (6 completed study, 6 w ithdrew due to disease progression, 3 died).	Complete response - 0% Partial response - 13% Stable disease - 71% Disease progression - 6% **All** tumours shrank by 16-100%. Durable responses in 23% patients out to 16 w eeks post treatment. Median PFS - 4.0 months; OS - 10.2 months	Neutropenia (Grade 3 toxicity - 23%).
DB2-202	Multi-centre, open label, dose escalating safety study in locally advanced **pancreatic cancer**.	200 & 400 Gy (12.8 & 26.4 MBq/mL)	6 patients (3 completed study, 3 w ithdrew due to disease progression).	Study stopped early - claims of 100% tumour control.	No Grade 3 or 4 toxicities related to OncoSil™.

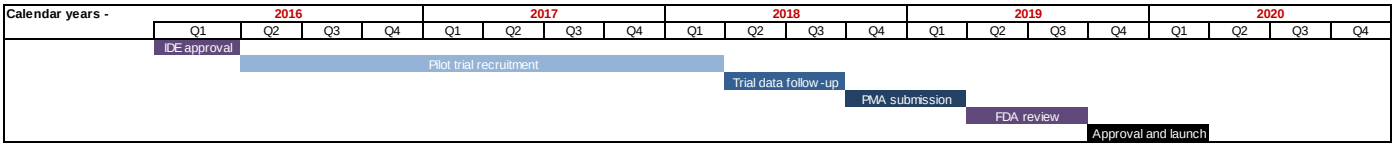
Source: WHTM Research

- **Recruitment, follow-up and PMA submission –** we have assumed a 2-year patient recruitment period, expecting that 20-30 clinical centres may be initiated. A successful study and FDA review process may support a US approval for OncoSil™ by 2020.

  The IDE study could also provide a clear catalyst for potential US partnering – the partner seeking to benefit by helping shape and direct the pivotal and subsequent studies required for OncoSil™ approval, clinical adoption and reimbursement.

US launch remains 4 years away, depending on the development pathway and trial outcomes

Figure 1: Indicative US regulatory timetable based on anticipated IDE trial design



Source: WHTM Research

[4] Consistent with Celgene's MPACT data. MPACT (Metastatic Pancreatic Adenocarcinoma Clinical Trial) was an open-label, randomized, international study conducted to evaluate the chemotherapy product ABRAXANE. MPACT demonstrated a statistically significant improvement in overall survival (OS) compared to patients receiving gemcitabine alone (median of 8.5 vs. 6.7 months, p = 0.000015). Celgene also looked at tumour response measures as secondary endpoints: a 31% reduction in the risk of tumour progression and an overall response rate (ORR) of 23% (ABRAXANE + gemcitabine) versus 7% (gemcitabine).

[5] Conventionally ORR comprises complete (100% shrinkage) and partial responses (50% or greater shrinkage).

CE Mark update – the European approval process has taken longer than the company anticipated, originally guiding to a Nov-15 outcome. Oncosil's decision to pool the pancreatic and liver indications in the single marketing submission has led to a lengthier review time by the Notified Body and its clinical examiners. The pancreatic and liver cancer indications do differ substantially in terms of tumour biology, aetiology and the proposed route(s) of OncoSil™ administration (endoscopic versus percutaneous injection).

The value of the CE Marking process, from our perspective, is the independent validation it can add. Although CE Marking helps clear a path towards first commercial sales in Europe and elsewhere, we do not expect sales traction to be at all broad, initially. Widespread clinical adoption of OncoSil™ depends on higher level evidence coming to hand, via well designed clinical trials (such as the IDE study) and through dissemination by early product adopters in the clinical oncology literature.

Valuation

Our price target is lifted to 50 cps, which is based on a risked, discounted cash flow (DCF) methodology. The upgrade is mainly in anticipation of the FDA clearing Oncosil's IDE study in the manner we have described here, and our increased confidence about the development program, given what we have gathered from our clinical conversations with the company and other sources.

We have developed an explicit forecast for OncoSil™ sales across three segments of the global cancer market: the US, five EU (UK, France, Germany, Italy and Spain) and APAC (principally Australia and New Zealand). We assess peak sales potential of ~US$350-400m for OncoSil™, with 75% of that relating to the treatment of locally advanced and/or metastatic pancreatic cancer in the US.

Table 2: DCF parameters for Oncosil valuation and target price

Valuation		The Inputs	
PV of FCFF ($M) =	53.8	Forecast period	FY16-30E
PV of Terminal Value ($M) =	138.5	Risk-free rate	3.50%
Value of Operating Assets of the firm ($M)	192.3	Risk premium	7.00%
- Net Debt ($M)	(5.0)	Beta	1.2
Equity value ($M) =	**197.3**	Clinical risk adjustment	50%
Shares on issue	356.2	WACC	14%
New issuance and options	147.3	Tg	3.50%
Fully diluted shares	503.5		
Value of Equity per share =	**$0.39**		
Value of HCC option	**$0.11**		
OSL Target Price	**$0.50**		

Source: WHTM Research

The most important valuation milestones in the near term are the IDE trial approval and a positive CE Marking decision, which might support valuations of up to $1.00 per share, on a 12-month view. If we completely de-risk the OncoSil valuation model (all clinical and development success probabilities set to 100%, discount rate set closer to 8-9% reflecting a more established medical device business), we can see potential valuations of $2.75 per share emerging over the next 3-5 years.

Oncosil Medical Limited (OSL)

BUSINESS DESCRIPTION

Oncosil Medical Limited (OSL) is developing a novel form of brachytherapy for the treatment of pancreatic and liver cancers. OncoSil™ provides a means of irradiating tumours from the inside, using microparticles impregnated with the radioactive isotope Phosphorus-32. OncoSil™ is expected to be granted CE Mark this year and be the subject of a large clinical trial in the US next year. We estimate a US$250m sales opportunity in the major pancreatic cancer markets.

INVESTMENT THESIS

OncoSil™ is an attractive product concept on account of its "single treatment" nature and dose intensity. We think the product deserves "accelerated review" status with the FDA and will find good adoption by interventional radiologists, if approved.

REVENUE DRIVERS

- Pricing and reimbursement
- Market penetration (new clinical centres/hospitals, physician acceptance)
- New markets (geographical, clinical indications)

BALANCE SHEET

- As at the 1HFY15 result, Oncosil had ~$7m in cash and no debt

MARGIN DRIVERS

- Gross margins sustainable at 80% or better
- Although SG&A structure is yet to evolve WHTMe long-term rates of ~40-50% achievable
- Reimbursement

BOARD

- Roger Aston (Chairman)
- Daniel Kenny (Managing Director)
- Martin Rogers (Non-Executive Director)
- Chris Roberts (Non-Executive Director)

KEY ISSUES/CATALYSTS

- CE Marking and European marketing
- Clinical trial design and FDA approvals

MANAGEMENT

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RISK TO VIEW

- Outlook depends on quality of evidence flowing from clinical trials
- Regulatory risks including manufacturing and quality
- Product safety
- Competitive risks in a busy oncology technology market

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Recommendation structure and other definitions

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