BELL POTTER

21 March 2016

Speculative
Refer to key risks on pages 4 and 26. Speculative securities may not be suitable for retail clients

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Oncosil Medical (OSL)

Emerging Therapy In Pancreatic Cancer

Recommendation
Buy (Initiation)
Price
$0.15
Valuation
$0.30 (unchanged)
Risk
Speculative

GICS Sector

Pharmaceuticals & Biotechnology

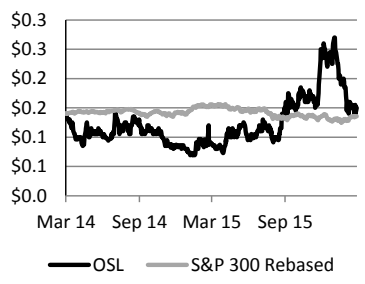
Expected Return	
Capital growth	**100%**
Dividend yield	**0%**
Total expected return	**100%**

Company Data & Ratios	
Enterprise value	**$45m**
Market cap	**$61m**
Issued capital	**421.9m**
Free float	**100%**
Avg. daily val. (52wk)	**$200,000**
12 month price range	**$0.07 - $0.28**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.19	0.17	0.09
Absolute (%)	-21.05	-9.09	72.41
Rel market (%)	-26.35	-14.31	83.67

Absolute Price



SOURCE: IRESS

Commercial Revenues Now Likely

OncoSil Medical is a medical device company with a brachytherapy product (OncoSil™) which we expect will shortly gain CE Mark approval for the treatment of pancreatic cancer.

A small clinical trial of the device in combination with chemotherapy indicated an extension in overall progression free survival versus the current standard of care in pancreatic cancer. The trial was not powered for statistical significance, however, the result was clinically significant and it is on this basis that the company applied for the CE Mark in July 2015. The company also applied for the CE Mark in Hepatocellular cancer. The approval process is ongoing. Subsequent requests for further information have delayed the approval beyond the company's envisaged timetable. However, it remains confident that the CE Mark will be granted in both indications.

The company is pursuing a regulatory pathway in the US in pancreatic cancer only. It has applied for an Investigational Device Exemption to allow it to conduct a clinical study. Details of the study are yet to be disclosed. We expect the primary endpoint will be localised progression free survival with a secondary endpoint of overall survival.

The company is led by CEO and MD Daniel Kenny, a highly experienced executive with significant international experience in medical device development, registration, marketing and sales. He is supported by a highly experienced management team that are capable of driving the commercialisation process. Following a recent capital raise the company has sufficient funds to commence the US trial and commercialisation within key markets in Europe.

Initiate With Buy Recommendation

OncoSil is now funded to drive commercialisation in Europe and commence a clinical study in the US. Pending the awarding of the CE Mark, we expect first commercial revenues in CY2016. We initiate cover with a Buy rating and valuation of $0.30.

Earnings Forecast

June Year End	FY15	FY16e	FY17e	FY18e
Revenues	2.8	2.6	3.9	5.1
EBITDA $m	-2.9	-6.3	-7.6	-10.5
NPAT (underlying) $m	-2.9	-5.8	-7.1	-10.0
NPAT (reported) $m	-2.9	-5.8	-7.1	-10.0
EPS underlying (cps)	-0.8	-1.4	-1.6	-2.1
EPS growth %	-43%	76%	14%	31%
PER (x)	-18.7	-10.6	-9.3	-7.1
FCF yield (%)	0%	-9%	-12%	-14%
EV/EBITDA (x)	-18.9	-8.7	-7.2	-5.2
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	-41.6%	-47.4%	-124.5%	-113.7%

SOURCE: BELL POTTER SECURITIES ESTIMATES

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Investment Case

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.

Key Short Term Catalysts

The company submitted the CE Mark dossier for pancreatic and primary liver cancer (HCC) in July 2015. We understand the few remaining questions regarding the dossier have now been addressed by OncoSil, while other matters have been closed out. The company expects the Notified Body will complete a final review in the near term. For these reasons we expect the CE Mark to be granted in both indications. The CE Mark will allow the OncoSil therapy to be marketed throughout the European Union and consequently first commercial revenues are expected in calendar 2016.

OncoSil has also filed for an Investigational Device Exemption (IDE) with an accompanying premarket approval (PMA) with the US FDA in pancreatic cancer only. Subject to the IDE being granted, OncoSil is likely to commence a clinical study to provide clinical evidence supporting use of the product in the US. 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.

The company is well resourced both financially and with human capital. Following its recent $10m capital raise (completed in Jan 2016) we expect it has $16m in cash which will be used to fund commercial role out in Europe and commence a clinical study in the US.

The company is led by Chief Executive and Managing Director Daniel Kenny. Mr Kenny joined the company in 2014 following a long career in the medical device and pharmaceutical industries, much of which he spent employed by leading global companies. He has extensive experience with clinical development, sales and marketing. In the 15 months since joining OncoSil he and the executive team have made significant progress in crucial areas that drive shareholder value including rationalisation of the clinical program and advancing regulatory approvals. Also joining the Board recently is Mr Chris Roberts, former long term CEO and Director of Cochlear Ltd.

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 expects to know within weeks whether it will be awarded the CE Mark that will 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 – We estimate that following the January 2016 capital raise, OncoSil has $16m of net 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 – OSL has applied for an investigational device exemption in the US for pancreatic cancer. It intends to conduct a clinical study to provide safety and efficacy data for use in this indication. Details of the study are yet to be disclosed. 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.

Overview of Pancreatic Cancer

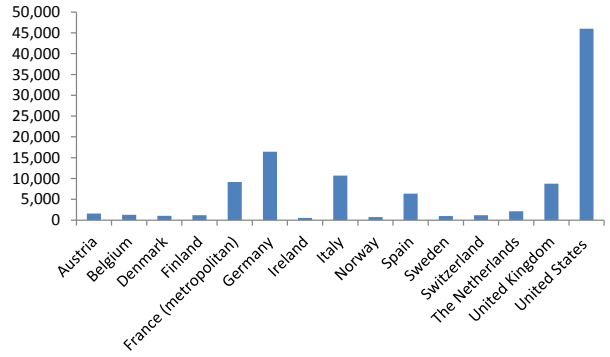
Pancreatic cancer rarely occurs before the age of 40, and more than half of cases of pancreatic adenocarcinoma occur in those over 70. Risk factors for pancreatic cancer include smoking, obesity, diabetes, and certain rare genetic conditions.

Pancreatic cancer is usually diagnosed by a combination of medical imaging techniques such as ultrasound or computed tomography, blood tests, and biopsy.

Incidence Rates - Across the entire European continent there are approximately 85,000 diagnosed cases annually. According to the American Cancer Society statistics, the number of new cases of pancreatic cancer in the US in 2015 was expected to be 48,960. The number of deaths is estimated as 40,560. Pancreatic cancer is the 4th leading cause of death in the US, after lung cancer (158,000), colon cancer (49,700) and breast cancer (40,730). Globally the number of new cases is estimated at ~338,000 annually.

Poor Prognosis – Median survival is a mere 8 months, 5 years survival is less than 5%.

Figure 1 - Annual Incidence rates - pancreatic cancer - major markets



SOURCE: GLOBOCAN

Of the countries selected in Figure 1 above, the combined European countries represent approximately 52,000 cases annually. We highlight these markets because they are likely to become the first target markets for OncoSil.

According to Globocan data the incidence rates range from 4 to 8 persons per 100,000 head of population with the vast majority of patients > 60 years of age. Of this diagnosed patient base, it is estimated that 85% are not suitable for surgery and may be future candidates for OncoSil.

DISEASE STAGING

The disease is normally diagnosed late when it is relatively advanced. The diagnosis is often late because patients typically have no symptoms in the early stages. Disease staging is also relevant because it provides a starting point to quantify the addressable market.

Figure 2 - Pancreatic Cancer - Staging

Stage	Status
I	Resectable (15% of patients at initial diagnosis)
II	Borderline resectable (tumours involved with nearby structures of the gut so as to be neither clearly resectable of unresectable)
III	Locally advanced unresectable (tumours involved with nearby structures of the gut that are unresectable despite absence of metastatic disease
IV	Disseminated disease - with numerous metastases

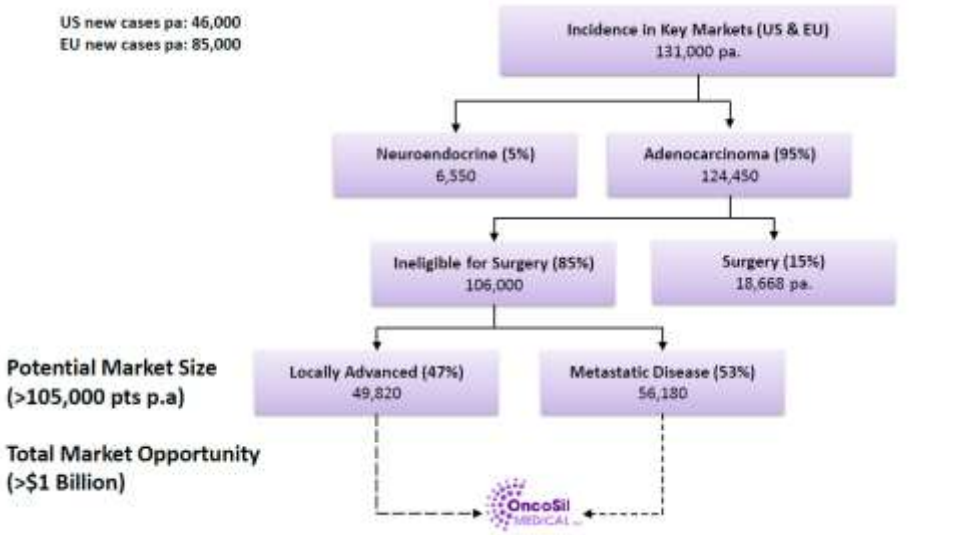
SOURCE: BELL POTTER SECURITIES

OncoSil is a treatment for the disease of the pancreas only and is ideally suited to stage II and III patients where the disease is too advanced for resection and has not yet spread to other organs or nearby structures, or where the extent of metastases is limited.

The prognosis for stage IV patients is poor, however, post mortem examination shows cause of death in at least 30% of patients is pancreatic failure as opposed to other organ failure (normally liver). Despite the poor prognosis for these patients, at least a portion of this group are likely to be suited to OncoSil.

The following chart outlines the patient pool by key criteria according to the company's estimates.

Figure 3 - Pancreatic Cancer Market Opportunity



SOURCE: COMPANY DATA

The inclusion or exclusion of the metastatic patient group is clearly important for determining the overall market size (and valuation).

In our assessment of addressable market, we assume 100% of both Locally Advanced and Metastatic Disease population are considered candidates. In relation to the Metastatic Disease population, post mortem studies have shown a divergent pattern of organ failure (including pancreatic failure) unrelated to clinical stage at initial presentation, treatment history or histopathological features. For this reason we include this patient group in the addressable market.

Overview of Hepatocellular Carcinoma Opportunity

In 2006 OncoSil was trialled in 8 patients with late stage primary liver cancer (Hepatocellular Carcinoma or 'HCC'). Patients received a single dose of the therapy via percutaneous implantation under local anaesthesia and were scanned at weeks 12 and 24.

All targeted tumours were responding at 12 weeks. Of the 5 patients who completed the trial, all experienced reductions in tumour volume and 3 of the 5 had a complete clearance of the targeted tumour burden.

Six of 8 patients reported 19 adverse events, but no serious adverse events were attributable to the study device.

Figure 4 - Study BIOSP - 201 in Primary Liver Cancer

Patient number	Last Visit Number (day)	% Change of Target Tumour Volume (mL) at Time of Best Response	Best Target Lesion Response	Target Lesion Response at Last Visit	New Lesions by Last Visit
001	Visit 5 (87)	-44%	SD	SD	No
002	Visit 7 (184)	-80%	PR†	PR	Yes
003	Visit 5 (86)	-16%	SD	SD	Yes
004	Visit 7 (182)	-43%	PR*	PR	Yes
005	Visit 7 (168)	-100%	CR††	CR	Yes
006	Visit 7 (176)	-100%	CR†	CR	No
007	Visit 7 (185)	-100%	CR*	PD	No
008	Visit 5 (94)	-35%	SD	SD	No

SOURCE: COMPANY DATA

Four of the patients had developed new lesions by the time of the last visit including one of the patients who had achieved complete clearance of the targeted tumour. The other four patients had no new tumours.

We regard this evidence as worthy of further investigation in a larger trial. By itself this trial was far too small to draw any conclusions regarding overall efficacy in a broader population.

A second trial in HCC was commenced but was terminated after only 11 patients had been recruited.

OncoSil therapy is targeted to inoperable liver cancer, but generally in earlier stage disease. Ideally the therapy is targeted to patients that have progressed after a liver resection or where the tumour(s) is otherwise inoperable (where there are less than 3 lesions each of modest size (<3cm in diameter).

A commonly used classification for liver cancer is the The Barcelona Clinic Liver Cancer (BCLC) staging classification. Stage A patients are early stage and suitable for resection. OncoSil is likely to be targeted to stage B and borderline stage C.

In contrast Sirtex Medical is currently running a major study in HCC. The SARAH[1] study is targeting a mix of patients including stages A, B and C. Stage D is end stage and these patients are excluded from the trial.

As neither product has reported result from a meaningful number of patients in clinical trials, it is far too early to draw conclusion regarding relative efficacy. Both products appear to have comparable safety records.

HCC is frequently associated with other liver disease including Hepatitis and Cirrhosis.

[1] SorAfenib vs Radioembolisation in Advanced Hepatocellular carcinoma

The incidence rate for HCC is Asian countries is up to four times higher than Europe and the US. For example, according to Globocan the incidence rate for HCC in Thailand and Singapore is 22 and 9.7 per 100,000 of population respectively. The incidence rate in mainland Europe is broadly estimated at between 5 and 6 per 100,000 head of population.

Regulatory Pathway

OncoSil has applied for the CE Mark to treat HCC based on the results from the 8 patient study in conjunction with the data supporting pancreatic cancer, thereby leveraging a larger data set for safety.

It is likely the CE Mark would be a precursor to approval in other markets including Singapore.

The standard of care for HCC varies across jurisdictions but generally is limited to chemotherapy and Sorafenib.

We understand that the CE Mark in HCC may approve OncoSil as a monotherapy. We expect oncologists may experiment with the OncoSil in combination with the standard of care. In order to become more broadly adopted and expand the label claim for use of the product, it is highly likely the company will need to run further clinical studies in combination with the standard of care.

There are no firm plans to seek approval of OncoSil to treat HCC in the US. The company may consider this option in the future.

The roll out of OncoSil in Asia is likely to commence in Singapore under the direction of Professor Chow (refer to section on Clinical Advisory Board).

The earnings forecast does not include significant revenues from the use of OncoSil in HCC. In our view the short to medium term focus for the company is going to be in Pancreatic Cancer where there is also a high unmet need.

Pancreatic Cancer - Treatment Landscape

If the pancreatic cancer is diagnosed early, surgery is an option and it may be curative. The downside to surgery is the nature of the procedure. Depending on the staging of the disease, the surgery may involve removal of part of the pancreas, part of the bowel, part of the stomach, the gall bladder, spline and part of the bile duct. Patients are generally quite elderly, hence this a major operation.

Even after the surgery, the cancer frequently returns and although these patients survive for longer than if surgery had not occurred, life expectancy is normally limited.

For inoperable cancers, the gold standard of treatment is Gemzar (Gemcitabine) which is a form of chemotherapy, in combination with Abraxane (Paclitaxel). The combination received FDA approval in 2013 following an 861 person multinational phase III trial in **metastatic pancreatic adenocarcinoma** (stage IV) (mPAC)[2].

Participants treated with Abraxane plus gemcitabine lived, on average, 1.8 months longer than those treated with gemcitabine alone (i.e. 8.5 months vs 6.7months).

Additionally, participants who received Abraxane plus gemcitabine experienced a delay in tumour growth (progression-free survival) that was, on average, 1.8 months later than the participants who only received gemcitabine.

Despite this survival benefit, the NICE in the UK has refused to approve the combination on the grounds that the cost does not justify its limited benefit. The NICE statement also referred to the serious side effect profile of the combination as impacting its view.[3]

Gemcitabine has been investigated in combination with other agents (such as cisplatin, oxaliplatin and 5-FU and irinotecan). Recent meta-analysis found that combinations give a marginal benefit in overall survival over gemcitabine monotherapy in the advanced setting with significant increases in survival[4].

The National Comprehensive Cancer Network (NCCN) does NOT recommend the combination of gemcitabine plus sorafenib (Nexavar).

Clinical trials evaluating the combination of gemcitabine with bevacizumab (Avastin) failed to show any improvement in overall survival. It is thought these biologics are less effective in pancreatic tumours than in other cancers essentially because of the avascular (low blood flow) nature of pancreatic tumours.

Chemoradiation for Locally Advanced Disease

There is a large body of evidence supporting the use of radiotherapy in combination with chemotherapy in unresectable pancreatic cancer.

A meta-analysis identified 15 randomised controlled trials (covering 1,128 patients) that compared chemoradiation to either chemotherapy or radiation in locally advanced patients. Whereas combined modality therapy significantly improved survival compared to **radiation alone**, survival was the same when compared to those receiving chemotherapy alone. In our view this suggests radiotherapy had little benefit.

A more recent phase III randomised trial which assessed gemcitabine compared with gemcitabine plus radiotherapy followed by gemcitabine alone in patients with locally advanced unresectable pancreatic cancer was closed due to poor recruitment. The analysis of 74 patients enrolled showed the median OS was significantly longer in the chemoradiation therapy arm of the study (11.1 months vs 9.2 months, P = 0.017), however

[2] Abraxane is marketed by Celgene in the US. It is indicated for pancreatic cancer and NSCLC. Guidance is for revenues of ~US$1bn in calendar 2015. Gemcitabine is now a generic drug.

[3] Abraxane is listed on the PBS in Australia at a cost of $16K per course.

[4] Refer to National Comprehensive Cancer Network treatment guidelines for pancreatic cancer.

there was no difference in PFS and the poor recruitment meant that the statistical results were weakened. It seems these encouraging results were not followed up, but nevertheless these results and others indicate that the combination of gemcitabine plus radiation therapy are worthy of further investigation.

Importantly the NCCN guidelines do not mention the use of brachytherapy for the treatment of pancreatic cancers. By implication the use of brachytherapy for the treatment of pancreatic cancer has not been widely tested or used.

OncoSil Therapy In More Detail

Brachytherapy is a form of radiation therapy for the treatment of hard to reach cancers. There are highly commercially successful precedents for localised radiation therapy in liver cancer (from Sirtex SIR spheres, BTG Theraspheres) and prostate cancer. Unlike external beam radiation (referred to in the NCCN treatment guidelines). OncoSil is a medical device, not a drug.

The OncoSil therapy consists of small particles of radioactive silicon and phosphorus. The phosphorus becomes radioactive after being placed in a nuclear reactor.

Once injected into the patient the radioactivity is emitted as beta particles (P^{32}) which travel only a short distance (5mm) from their source, hence there is minimal damage to other organs. It is well suited to tumours to maximise local effects while minimising systemic toxicity.

External beam radiation on the other hand uses very high energy subatomic particle streams being either Gamma Rays or X Rays capable of causing significant damage to other organs in the gut making it unsuitable for treatment of pancreatic cancer.

The first target for the therapy is Pancreatic Cancer, however, trials have also been conducted in Hepatocellular cancer.

Delivery – OncoSil is suspended in a shielded syringe in the operating theatre where a physician will make the injection of the device into the pancreas.

An endoscope is guided into the patient's stomach and into the first part of the small intestine (the duodenum). Ultrasound is used to image the tumour in the pancreas, then a large needle is extended from the end of the scope through the wall of the intestine into the pancreas and into the tumour. The position of the needle and the tumour is confirmed using real time imaging, when all is in place OncoSil is injected directly into the tumour.

The entire procedure (excluding the work up) is completed within a few hours and patients typically walk out of the hospital on the same day.

The procedure is performed by a gastroenterologist as part of a multi-disciplinary team including oncologists and radiation oncologists. The risk in the surgery is considered low and is likely to diminish with experience (of the medical team responsible for prescribing and delivering this therapy).

The half-life of OncoSil is 14 days, with all traces of radioactivity gone at 3 months.

Safety – Evidence from clinical trials conducted to date shows the treatment to be safe. There have been no serious adverse events (SAEs) arising from the treatments (albeit some patients showed side effect consistent with the chemotherapy).

EVIDENCE FROM CLINICAL TRIALS

A pilot study of OncoSil in pancreatic cancers was completed nearly a decade ago and was presented at ASCO in 2008. The key points from the study were as follows:

Study design – 17 patients all with advanced pancreatic cancer, single arm study. Of the 17 patients, six had locally advanced disease and eleven had metastatic disease. In addition to OncoSil (patients received 100 Gy), gemcitabine (chemotherapy) was also administered.

Result summary:

Safety:

- Safety – No serious adverse events reported in relation to the P^{32}. A small percentage of patients suffered grade 3 serious adverse events typically

associated with the chemotherapy. These included nausea & vomiting (1), Abdominal pain (1) and neutropenia (2).

- No significant systemic leakage of P^{32} from the implantation.

Efficacy

- The overall response rate was 82%;
- 4 partial responses, 10 stable disease and 3 patients progressed. 50% of patients experienced at least a 30% reduction in tumour size;
- Patients experienced an average pain reduction of 35% with a maximum reduction of 69% between weeks 8 and 11 following implant;
- Median progression free survival was 121 days; and
- Median overall survival was 309 days (10 months) as compared to 8.5 months with the combination of gemcitabine and abraxane and 5.7 months with gemcitabine alone.

In summary, the clinical trial provided evidence of efficacy across key measures of reduction in tumour size, pain levels, progression free survival and overall survival.

The patient group appears to have included a mix of stage III and stage IV and was comparable to the patient group in the Abraxane approval study. For this reason we consider the comparison of survival data from the OncoSil pilot study remains valid.

In our opinion, based on these results – albeit in just 17 patients, there is sufficient evidence to warrant further investigation of OncoSil in combination with current standard of care.

A second pilot study was conducted in 2009 for the purposes of determining the optimal dose. The study examined 6 patients.

Patients received either 200Gy or 400Gy[5] as a single injection. We understand the optimal dose for OncoSil will remain at 100Gy.

[5] Gy or Gray Units is a measure of dose strength in nuclear medicine.

Regulatory Pathway For Key Markets

Europe

The key markets in Europe are listed in Figure 1.

The results from the pilot study underpinned the company's application for CE Mark approval in late calendar 2015. The Company was granted a fast track review for its CE Mark with the European regulator in October 2015 and expects to receive the outcome of its CE Mark application in the near future – either late March or early April 2016.

The CE Mark will allow it to commence marketing the product across Europe. It is apparent that CE Mark is available without efficacy data from a major study, however, OncoSil has ISO certification (ISO 13485). The certification is issued by the British Standards Institution (BSI) and is a requirement for the CE Mark. ISO 13485 is internationally recognised as the best quality practice within the medical device industry.

In addition to allowing OncoSil to be marketed in Europe, the CE mark will also facilitate sales in other key markets including Aust/NZ, Canada and Singapore.

US

OncoSil is classified as a Class III medical device for the purposes of the US Food and Drug Administration.

In December 2015 the company filed an Investigational Device Exemption (IDE) with the FDA. This is the first step towards securing commercial approval for OncoSil under a pre-market approval (PMA).

Subject to an IDE being granted, OncoSil will commence a clinical study to support the PMA. A PMA will allow the company to commercially market OncoSil™ in the USA.

The Company formally filed its IDE submission on 10th December 2015 after successfully completing a lengthy pre-IDE process. The pre-IDE process involved an FDA review of the proposed clinical investigational plan including the endorsement of clinical endpoints and outcomes measures.

The involvement of the FDA at this early stage is highly significant. While the company has not yet published the details of its clinical program in the US we expect significant changes from the pivotal trial program discussed by previous management.

US clinical study design considerations

The submission of the IDE to the US FDA follows an extensive preparatory period. If the IDE is granted it will provide the company and investors with assurance that the clinical program that may lead to approval in the US is rigorous.

OncoSil has not yet revealed the details of its clinical program in the US other than to say it is pursuing an investigational device exemption (IDE) accompanied by a premarket approval (PMA). Normally a new device requires a small pilot study followed by a larger pivotal study, however, we suspect OSL will pursue the more aggressive Expedited Access Pathway (EAP).

CEO Daniel Kenny is highly skilled in regulatory matters and also well connected amongst high profile US consultants familiar with these matters and close to the FDA. If OSL does get the EAP, it is likely to be driven by the fact that OncoSil is the first intra-tumoral device seeking approval for pancreatic cancer. It also needs to satisfy one of the following[6]:

- It may offer significant, clinically meaningful advantages over existing therapy, or
- The availability of the device is in the best interest of patients.

Given that there are 40,000+ deaths a year in the US from this disease, it is hard to see that this device is not in the best interest of patients.

Prospective Trial Design – key points

- Approximately 200 – 250 late stage (stage II, III and IV) pancreatic cancer patients;
- Randomised 1:1; and
- Treatment arm - Combining OncoSil with Gemcitabine and Abraxane vs Control arm of Gemcitabine and Abraxane (standard of care).

The number of patients potentially involved is higher than for a normal pilot study, however, this is necessary in order to provide sufficient evidence regarding safety and efficacy for approval.

We estimate cost per patient at ~US$85,000, hence the cost of this trial is estimated at between US$17m – US$21m.

OncoSil is unlikely to replace surgery as a potentially curative first treatment option, hence stage 1 patients will probably be ineligible for this trial. Borderline surgery cases (stage II) may be included where treating physicians have identified other reasons why a patient may not be a surgical candidate (e.g. age, generally poor health, other co-morbidities).

Prospective Clinical Endpoints

- **Dual Primary Endpoints**

  - Localised progression free survival within the pancreas (LPFS); and

  - Clinical benefit (study unlikely to be powered for statistical significance).

- **Dual Secondary endpoints**

  - Overall survival (OS); and

  - Pain management and safety.

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

[6] Further criteria are set out on the FDA's web page. EAP only applies to treat or diagnose life threatening disease.

achieved at least 30% reduction in tumour volume) is likely to attract the attention of oncologists.

We expect OncoSil therapy to provide a significant advantage over current standard of care in LPFS

OncoSil is a localised therapy being combined with two chemotherapy (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).

There is no data for Local Progression Free Survival, but we do expect OncoSil therapy to be highly effective at controlling the disease within the pancreas, hence LPFS should exceed PFS.

The secondary endpoint of OS is also logical. If the trial meets this endpoint, it would be highly valuable data for oncologists (let alone shareholders) and potentially provide evidence for adoption as standard of care (which would most likely need to be supplemented by larger randomised study).

It is likely many patients on the trial will have between one and three metastases, hence any extension in overall survival is likely to be measured in months. In order to prove statistical significance on OS, OncoSil would have required to conduct a larger study and this is not appropriate in the current circumstances.

ADMISSION CRITERIA

Admission criteria to the trial is likely to be tight, particularly for patients with metastatic disease. The likelihood is that even patients who show no sign of metastatic disease at initial diagnosis probably will have undetectable tumours which will grow during the trial period. It is for this reason that the study is likely to avoid overall progression free survival as an endpoint. Also by excluding patients with multiple metastases (i.e. >3), the likelihood of achieving the overall survival benefit is increased.

In the phase III MPACT study which led to the approval of Abraxane, the majority of patients had multiple metastatic sites including liver and lung metastases. OncoSil has no impact outside of the pancreas hence would have no chance of halting or slowing any metastases that may exist outside of the pancreas at the time treatment commences**. For this reason we expect no improvement in overall progression free survival – hence this measure is unlikely to be listed as even a secondary clinical endpoint**[7]**.**

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.

IS THE ABSENCE OF A SYSTEMIC RESPONSE LIKELY TO SLOW ADOPTION ?

It is likely there will be a section on the oncology community that will view the likely absence of a systemic benefit from OncoSil as a reason not to use this device. Notwithstanding, as more than 50% of patients have metastatic disease at the time of diagnosis it is a question of which organ failure(s) will lead ultimately result in patient death.

Fortunately there is some good, recent research on this topic. Donahue[8] examined cause of death amongst 76 pancreatic cancer patients. We summarise the findings below:

[7] For further detail regarding the MPACT study, refer to http://www.abraxane.com/hcp/metastatic-pancreatic-cancer/efficacy/trial-design/mpact-patient-summary/

[8] Donahue et al, American Society of Clinical Oncology, Vol 27, Number 11

Figure 5 - Summary of findings from Donahue et al

Disease stage at initial diagnosis	Patient numbers	%	Median PFS (months)	Median OS (months)	Treatment	At Post Mortem
Stage I/II	22	29%	14	24	Surgery and chemotherapy	2 patients died of other causes, 3 had recurrent pancreatic cancer, 4 had metastic disease and 13 had recurrent carcinoma and metastatic disease
Stage III	18	24%		12	Chemo/Radiotherapy	72% had evidence of metastatic disease plus the local carcinoma
Stage IV	36	47%		6	Chemotherapy	97% had evidence of metastatic disease plus the local carcinoma
	76					

SOURCE: BELL POTTER SECURITIES

The examiners determined that 30% of all patients died from locally destructive pancreatic cancer, and 70% died with widespread metastatic disease.

The divergent patterns of failure found at autopsy were unrelated to clinical stage at initial presentation, treatment history or histopathologic features.

- Overall 88% of patients had metastatic disease.
- The extent of metastatic disease varied dramatically, ranging from 1 to 10 metastases to more than 1,000. The most common sites for metastases were liver, peritoneum and lung in that order.

The examiners determined the following clinical implications from these findings (which we have only partially summarised above). We consider these are crucial for modelling the addressable market for OncoSil.

Figure 6 - Conclusions from post mortem studies in pancreatic cancer

Clinical Implication	For OncoSil
Not all patients with pancreatic cancer die of widespread metastatic disease. 12% of patients had no evidence of metastasis and this finding was not unique to patients who underwent treatment, nor was it specific to patients initially diagnosed at an early stage.	Patients with no metastases at diagnosis, and not suitable for surgery are ideal candidates for OncoSil.
In patients with locally advanced disease with either no or limited metastases, the cause of death were related to complications of the local disease.	Pancreatic organ failure was cause of death. These patients are well suited to OncoSil.
In patients with significant metastatic burden and limited local disease, death was more commonly related to organ failure and cachexia[9].	OncoSil is likely to have minimal benefit for patients with extensive metastatic disease. OncoSil may provide a benefit for patients with limited metastases.

SOURCE: BELL POTTER SECURITIES

In a separate study which stringently evaluated cause of death related to pancreatic cancer, Nakahashi[10] et al found that the number of patients with extensive metastatic disease leading to hepatic dysfunction and death was relatively small, and the presence of isolated hepatic metastases were often clinically insignificant compared to the complications that arose from locally destructive growth of the primary carcinoma.

Conclusions

In our view it is not unreasonable to conclude that by extending the localised PFS period of the primary tumour (via the use of OncoSil), the likelihood of an OS benefit is raised.

In order to be recognised as standard of care, it will be necessary to demonstrate an overall survival benefit. This may come via a subsequent clinical trial but is not yet contemplated.

[9] Weakness and wasting of the body associated with severe chronic illness.

[10] Nakahashi C et al the impact of liver metastasis on mortality in patients with locally advanced or resectable pancreatic cancer Int J Gastrointest Cancer 33:155 – 164 , 2003.

In the interim we consider it quite reasonable for oncologists to view reduction of tumour burden in the primary cancer and pain reduction as worthwhile outcomes – in fact these are the objectives of current gold standard treatment.

MORE CLINICAL WORK POTENTIALLY REQUIRED

The completion of the US clinical study will mark an important milestone in the development of OncoSil in pancreatic cancer, but as was the case for Sirtex in mCRC, more clinical studies will be required to promote the use of this therapy to standard of care.

For pancreatic cancer, this is likely to include the initiation of a larger randomised study with the primary endpoint of overall survival. If the OncoSil Board decides to commit to an overall survival benefit study, it would only do so having carefully considered the OS outcomes of the clinical study currently being contemplated.

The cost of an overall survival benefit study is likely to run to tens of millions of dollars as it would need to be appropriately powered for statistical significance and involve several hundred patients at least.

We estimate the timing and cost of the clinical trial being contemplated for US as follows.

Figure 7 - Suggested timing and cost of pancreatic cancer trial (US$)

			Timing and cost (min)			
Patient numbers	**Indicative Cost**	**Time to complete**	**FY17**	**FY18**	**FY19**	**FY20**
200 to 250	A$23m - A$29m	Min 3 years	1.1	5.7	9.0	6.8

SOURCE: BELL POTTER SECURITIES ESTIMATES

Figure 7 assumes OSL pursues Expedited Access Pathway. By comparison a small US pilot study would be significantly less costly, however, this would not lead to the PMA being granted and would require a follow on pivotal study.

Clinical Advisory Board

Dr. Joseph Michael Herman, M.D., M.Sc.

Co-Director, Pancreatic Cancer Multidisciplinary Clinic, Associate Professor of Radiation Oncology and Molecular Radiation Sciences – Johns Hopkins University, Baltimore USA.

The involvement of Dr Herman is important, not only because of this clinical expertise, but also because Johns Hopkins is a high volume, prestigious medical institution in the United States. Its participation in the clinical trial is important for overall credibility and in achieving accelerated recruitment.

Dr Herman is a panel member for the NCCN Guidelines on pancreatic cancer.

Professor Pierce Chow

Professor Chow was recently appointed as Chairman of the Company's primary liver cancer Scientific Advisory Board. Professor Chow is acknowledged as a global leader in oncology, with particular emphasis on primary liver cancer, and the development of medical devices, and his appointment represents a major endorsement of OncoSil's plans to actively pursue the primary liver cancer indication. He is Professor at the Duke-NUS Graduate Medical School and Senior Consultant Surgeon at the National Cancer Centre in Singapore and the Singapore General Hospital. Professor Chow is also a member of the OncoSil Pancreatic Cancer Clinical Advisory Board.

Professor Stephen Clarke

Professor Clarke now practices in Sydney and has an extensive resume including more than 100 publications in peer reviewed journals.

Professor Richard Epstein

Professor Epstein has an extensive career in Cancer Research and now consults to the Garvan Institute for Medical Research and maintains a practice at St. Vincent's in Sydney.

Professor Dale Bailey, Principle Physicist, Department of Nuclear Medicine, Royal North Shore Hospital, Sydney.

Financials

As at the last reporting date (31 December 2015) cash reserves were $5.9m.

The current (pre commercial revenue) cash burn is between $5.5m and $6.0m per year. The net cash burn is reduced to approximately $3.0m to $3.5m after the R&D tax credit.

BALANCE SHEET

Total assets at 31 December 2015 were $7.5m.

OSL wrote off the entire $2.6m balance of intangible assets in the restated financial statements for the year ended 30 June 2014. It has not capitalised any development cost since then.

The forecast assumes this accounting policy continues. The policy of writing off 100% of R&D is consistent with US GAAP but not Australian IFRS.

All production is outsourced to specialised manufacturers, hence there will be no issue with the carrying value of production assets going forward.

We consider these accounting policies conservative, but consistent with US peers. By contrast the local peer in brachytherapy – Sirtex Medical does capitalise large portions of its R&D cost, however, it also generates significant revenues.

INCOME STATEMENT FORECASTS

Appendix 1 includes the key assumptions relating to revenue forecasts.

We expect first revenues from dose sales in Europe and Asia Pacific in calendar 2016. Commercial sales in the US are not expected until at least FY19 following completion of a clinical trial.

Other key assumptions:

- CE Mark is received in April/May 2016. This may lead to first commercial sales in calendar 2016 and the hiring of a contract sales force with an annual cost of $2m;
- Long term gross margin of 80% - which implies cost per unit of US$3,000 based on US$ selling price of US$15K;
- Large ramp up in the cost base from FY17, mainly attributable to the extensive business development program that will be required once the initial CE Mark is obtained;
- We have not included the cost of a larger clinical trial aimed at proving an overall survival benefit. Despite this, based on the success Sirtex has enjoyed in growing its dose sales over recent years (also without the benefit of proof of an overall survival benefit for mCRC patients) there is a reasonable likelihood of ongoing dose sales growth for OncoSil.
- If we assume the cost of the clinical trial in the US runs as planned (i.e. min A$22m over 3 to 4 years), and revenues are also in line with forecast, OSL may require further capital in FY18;
- The financial forecast assumes the company partners the product for roll out across jurisdictions including China and Japan. We assume an initial upfront receipt to OncoSil of $40m in 2019.

There are many variables in these assumptions, perhaps the most important of which is that the clinical study in the US proceeds smoothly. With only a handful of patients ever having been dosed with OncoSil there is considerable scope for learning.

OTHER KEY ITEMS

Beyond the short term regulatory and clinical approvals, OncoSil's key challenges are as follows.

Business Development

OncoSil has practically no profile today. The level of awareness amongst key opinion leaders in the US and Europe is likely to be low. In order to address this, it will require extensive investment in business development activities amongst Medical Oncologists, Interventional Oncologists and GI surgeons, all of whom will require specialist training;

- Hospital accreditation – OncoSil is a radioactive device and requires specialist skills for storage and use; and
- OSL has its training team in place now, ready for immediate engagement with early adopter hospitals in Europe and Australia.

Funding

In the EU, initial commercial sales of OncoSil will require self-pay from patients. Each jurisdiction has its own funding mechanism and OSL will be required to pursue these on a country by country basis.

Within the UK for example, funding levels vary from NHS Trust to Trust depending on the priorities of the each. Successful clinical outcomes from a subsequent clinical trial including an overall survival benefit will assist in promotion of this therapy for additional funding.

In Australia, it is likely there will be some relief funding available, as was the case for Sirtex. OSL will purse immediate registration of the product with the TGA in Australia once the CE Mark is obtained. This would allow use of the product in leading public hospitals.

In the US, it is likely OSL will be required to pursue a new code for OncoSil therapy. If the data from the clinical trials support favourable safety and efficacy conclusions, particularly if the US FDA grants a PMA, both Medicare in the US and private payers are likely to support reimbursement.

Manufacturing

OncoSil outsources 100% of production to four key external vendors, each of whom handles a discrete stage of in the manufacturing process.

- Atomising Systems(UK) for micro particle atomisation and classification;
- High Force (UK) for micro particle acid etching;
- LyoContract (Germany) responsible for diluent product; and
- Eckert & Ziegler in Germany, for target preparation and radiopharmaceutical preparation and packaging.

As volumes increase OncoSil does intend to develop internal manufacturing capability, albeit this is likely to supplement external vendors who will remain as long term partners.

The OncoSil product poses no threat to humans when handled according the proper practices. The potential threat to the business is more the ongoing access to the appropriate manufacturing facilities.

The half-life of P^{32} is 14 days, hence there is considerably greater flexibility with regard to shipping to treating hospitals. Key markets in the US and Europe are all accessible within 24 hours of manufacturing.

Corporate History

The company underwent a name change from NeuroDiscovery to OncoSil Medical in May 2013. The name change followed the acquisition by NeuroDiscovery of intellectual property assets from the UK based company Enigma Therapeutics.

The two clinical trials of OncoSil referred to earlier in this paper were completed by Enigma Therapeutics in approximately 2008.

The fair value of consideration for these assets as disclosed in the June 2013 Financial Statements was $2,647,726 and included 75m OncoSil shares @3.4cents and cash of US$100,000.

Shortly after the acquisition, OSL raised a further $10m from shareholders to continue the development of the technology.

OncoSil Medical Ltd owns the exclusive global license for OncoSil™ containing certain radioactive isotopes for use in all solid tumours. The license is granted from pSiMedica Ltd, a subsidiary of pSividia Corp (ASX: PVA).

OncoSil is required to make the following royalty payments for the term of the license:

- Up to US $100K annually to support existing patents (although the terms of this are not disclosed); and
- 8% of future net sales. The rate halves if a generic competitor emerges.

The patents over the technology remain the property of pSiMedica Ltd.

In the US, the "Devices and Methods for the Treatment of Cancer" patent over the technology expires in 2022.

We understand the key Devices and Methods patent for key markets in Europe also expire in 2022.

Figure 8 - History of Capital Raising

Fiscal Yr	Method	Raising $m	Price (cps)
2016	Placement	10.0	22
2014	Placement and SPP	10.3	13
2013	Placement	1.7	2.5
2011	Placement	1.1	2.5
		23.1	

SOURCE: COMPANY DATA

Figure 9 - Key Shareholders

Key Shareholders	# shares	
Regal Funds Management	45.5	10.8%
Webinvest	30.6	7.3%
Roger Aston (Chairman)	13.0	3.1%
Daniel Kenny (CEO)	12.0	2.8%
Newton More Biosciences	11.0	2.6%
Martin Rogers - Non Exec Director	10.3	2.4%
Shares on issue	**421.9**	

SOURCE: COMPANY DATA

Valuation

We have determined the valuation using a risk adjusted discounted cash flow model. OncoSil is not yet approved in key jurisdictions where it intends to derive revenues and accordingly the risk adjustments reflects this key item. As approvals are received the risk associated with the forecast cash flows will reduce.

The revenue projections do not include allowances for HCC related cases. OncoSil has not been used in combination with the current standard of care in HCC, therefore we expect adoption rates will be modest – at least initially. It is likely the company will be required to conduct a clinical study in combination with standard of care in this indication in order accelerate revenues.

The company may require further capital from shareholder in order to fund the clinical trial in the US and support the roll out of OncoSil in Europe. There are numerous factors which influence the timing of this event (if any) including sales revenues and the timing of the clinical program in the US. The forecast assumes a second capital raising in 2018 for $13m. The discounted cash flow calculation assumes the diluted shareholder base from this subsequent capital raising.

We summarise the outputs from the DCF model as follows:

Figure 10 – Valuation assumption for DCF

Underlying Interest Rate	5.0%
Credit Spread	3.0%
Pretax Cost of Debt	8.0%
Assumed Corporate Tax Rate	30.0%
After Tax Cost of Debt	5.6%
Risk Free Rate	6.3%
Equity Beta	1.7
Equity Risk Premium	5.0%
Cost of Equity	14.8%
Gearing (D/D+E)	0.0%
Asset Beta	1.15
WACC	14.8%
Valuation Base Date	30-Jun-16
Explicit Forecast Period (Years)	10
Terminal Year (TY)	30-Jun-26
Terminal Grow th Rate	2.0%
Terminal Year Multiple	6.9
Firm-based DCF Valuation	$0.30
Franking Credits valued at	30%
IRR at Current Price	21.5%
IRR at DCF Valuation	13.7%

SOURCE: BELL POTTER SECURITIES ESTIMATES

The initial valuation is set at $0.30.

Board and Management

The Board is dominated by Independent Directors.

DR ROGER ASTON – NON EXECUTIVE CHAIRMAN (HOLDS 13M SHARES)

We consider Dr Aston is an Independent Director.

Dr Aston has been closely involved in start-up companies and major pharmaceutical companies. Aspects of his experience include FDA and EU product registration, clinical trials, and fundraising.

Dr Aston was Executive Chairman of Mayne Pharma Group from 2009 to 2011 and later, CEO of Mayne Pharma. Other Directorships Regeneus Ltd, Immuron Ltd, Pitney Pharmaceuticals Ltd, PharmAust Ltd and ResApp Ltd.

MR DANIEL KENNY - CEO AND MANAGING DIRECTOR (HOLDS 12M SHARES)

Since his appointment in November 2014, Mr Kenny has transformed the outlook for OSL. He acted quickly to halt the enrolment of a pivotal study that was not optimal and proceeded to redraft the OSL clinical program. He has attracted a stream of high quality new appointments to key positions including Chief Medical Officer, Medical Affairs, Regulatory Affairs and Manufacturing. We expect this team will carry the development of OncoSil well into commercialisation.

Mr. Kenny has 30 years' experience in the global pharmaceutical and medical device industry. His career experience extends to FDA & EU product and device registration, clinical development, marketing & sales, in-licensing and business development. Prior to working with OncoSil Medical Mr Kenny held senior executive appointments with ABIVAX, Baxter International and Roche.

DR. CHRIS ROBERTS – NON EXECUTIVE DIRECTOR (NIL SHARES OWNED)

Dr Roberts is a highly experienced director and senior executive with 40 years' experience in the medical innovation space. During this time he has served on the boards of a number of ASX listed companies as well as research institutions and government entities. Most notably Dr Roberts was a previous Chairman of Sirtex Medical Ltd.

He is well known to investors via his recently concluded 11 year tenure as CEO of Cochlear Ltd during which time the company experienced a vast expansion of its revenues and markets. Prior to Cochlear he was a senior executive at Resmed and he remains a Non-Executive Director of the company. He sits on the Board of numerous not for profit entities many of which are associated with medical research, technology and innovation.

MARTIN ROGERS – NON EXECUTIVE DIRECTOR (HOLDS 10.3M SHARES AND 19M OPTIONS)

Mr Rogers is start-up investor and company director. He is also Chairman of Actinogen Ltd.

Appendix 1 – Revenue Forecasts

	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
United States										
Incidence of Pancreatic Cancer	46,000	46,460	46,925	47,394	47,868	48,346	48,830	49,318	49,811	50,310
Incidence of adenocarcinoma (95%)	43,700	44,137	44,578	45,024	45,474	45,929	46,388	46,852	47,321	47,794
Unresectable patients (85%)	37,145	37,516	37,892	38,271	38,653	39,040	39,430	39,824	40,223	40,625
Revenue per dose US$'000				16	17	17	18	18	20	20
Dose sales per sales person				20	70	150	300	400	480	576
Revenue per sales person				320	1190	2550	5400	7200	9600	11520
Sales force				7	10	10	10	15	20	20
Dose sales				140	700	1,500	3,000	6,000	9,600	11,520
Dose sales US$'000				2,240	11,900	25,500	54,000	108,000	192,000	230,400
FX Rate				0.7	0.7	0.7	0.7	0.7	0.7	0.7
AUD Revenues				3,200	17,000	36,429	77,143	154,286	274,286	329,143
Implied market penetration				0.4%	1.8%	3.8%	7.6%	15.1%	23.9%	28.4%
EMEA										
Incidence of Pancreatic Cancer	85,000	85,850	86,709	87,576	88,451	89,336	90,229	91,132	92,043	92,963
Incidence of adenocarcinoma (95%)	80,750	81,558	82,373	83,197	84,029	84,869	85,718	86,575	87,441	88,315
Unresectable patients (85%)	68,638	69,324	70,017	70,717	71,424	72,139	72,860	73,589	74,325	75,068
Revenue per dose EUR$'000	6	6	6	6	7	8	8	8	9	9
Dose sales per sales person		20	50	80	150	200	300	400	480	576
Revenue per sales person		120	300	480	1050	1600	2400	3200	4320	5184
Sales force		5	5	7	7	7	8	10	15	20
Dose sales	10	100	250	560.0	1,050.0	1,400.0	2,400.0	4,000.0	7,200.0	11,520.0
Dose sales €'000	60	600	1,500	3,360	7,350	11,200	19,200	32,000	64,800	103,680
FX Rate	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
AUD Revenues	100	1,000	2,500	5,600	12,250	18,667	32,000	53,333	108,000	172,800
Implied market penetration	0.0%	0.1%	0.4%	0.8%	1.5%	1.9%	3.3%	5.4%	9.7%	15.3%
Australia/NZ										
Incidence of Pancreatic Cancer	3,600	3,636	3,672	3,709	3,746	3,784	3,821	3,860	3,898	3,937
Incidence of adenocarcinoma (95%)	3,420	3,454	3,489	3,524	3,559	3,594	3,630	3,667	3,703	3,740
Unresectable patients (85%)	2,907	2,936	2,965	2,995	3,025	3,055	3,086	3,117	3,148	3,179
Patients with three or less metastatic sites (85%)	2,471	2,496	2,521	2,546	2,571	2,597	2,623	2,649	2,676	2,702
Revenue per dose A$'000		10	10	10	11	11	11	11	11	11
Dose sales per sales person		10	20	50	70	100	100	100	100	100
Revenue per sales person		100	200	500	770	1100	1100	1100	1100	1100
Sales force		2	2	2	2	3	3	3	3	4
Dose sales		20	40	100	140	300	300	300	300	400
Dose sales A'000		200	400	1,000	1,540	3,300	3,300	3,300	3,300	4,400
FX Rate		1.0	1.0	1.0	1.0	1.0	1.0	1.0	2.0	3.0
AUD Revenues		200	400	1,000	1,540	3,300	3,300	3,300	1,650	1,467
Implied market penetration		0.8%	1.6%	3.9%	5.4%	11.6%	11.4%	11.3%	11.2%	14.8%
Total Revenue A$m - prior to risk adjusment	0.1	1.2	2.9	9.8	30.8	58.4	112.4	210.9	385.6	506.3
Total doses sold	10	120	290	800	1,890	3,200	5,700	10,300	17,100	23,440
Average revenue per dose A$'000	10.0	10.0	10.0	12.3	16.3	18.2	19.7	20.5	22.5	21.6

OncoSil Medical
as at 21 March 2016

Recommendation	Buy, Speculative
Price	$0.15
Valuation	$0.30

Table 1 - Financial summary

Profit & Loss (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Year Ending June					
Dose sales (units)	-	10	120	290	800
Net revenue from product sales	-	0.1	0.9	2.1	7.2
COGS	-	- 0.1	- 0.8	-0.9	-1.4
Gross profit	-	0.0	0.4	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**	**2.6**	**3.9**	**5.1**	**50.2**
Other expenses	**-5.7**	**-8.8**	**-11.1**	**-14.7**	**-17.2**
EBITDA	**-2.9**	**-6.3**	**-7.6**	**-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	-6.3	-7.6	-10.5	31.5
Sundry income	0.0	0.5	0.5	0.5	0.5
Pre tax profit	-2.9	-5.8	-7.1	-10.0	32.0
Tax expense	-	-	-	-	-
NPAT- normalised	-2.9	-5.8	-7.1	-10.0	32.0
Net abnormal items	-	-	-	-	-
Reported NPAT	-2.9	-5.8	-7.1	-10.0	32.0

Cashflow (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Gross cashflow	-0.3	-6.3	-7.9	-10.5	30.9
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	-5.8	-7.4	-10.0	31.4
Maintenance capex	0.0	0.0	0.0	0.0	0.0
Capitalised clinical trial spend	0.0	0.0	-1.1	-5.7	-9.0
Free cash flow	-0.1	-5.8	-8.6	-15.7	22.3
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	0.0	12.0	0.0	13.0	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)	6.2	(8.6)	(2.7)	22.3
Cash at beginning of period	6.2	6.1	12.3	3.7	1.0
Cash at year end	6.1	12.3	3.7	1.0	23.2

Balance Sheet (A$m)					
Cash	6.1	12.3	3.7	1.0	23.3
Receivables	0.1	0.1	0.2	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	-	-	1.1	6.8	15.8
Total assets	7.4	13.7	6.6	9.8	42.0
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	13.2	6.1	9.2	41.2
Share capital	23.8	35.8	35.8	48.9	48.9
Retained earnings	(18.7)	(24.5)	(31.6)	(41.5)	(9.5)
Reserves	1.9	1.9	1.9	1.9	1.9
Shareholders Equity	7.0	13.2	6.1	9.2	41.2

Last sale 17/03/2016	0.15
Recommendation	Buy (Spec)
Issued Capital	421.9
Market Cap	70.8

Valuation Ratios (A$m)	FY15	FY16	FY17e	FY18e	FY19e
Reported EPS (cps)	-0.8	-1.4	-1.6	-2.1	6.8
Normalised EPS (cps)	-0.8	-1.4	-1.6	-2.1	6.8
EPS growth (%)					
PE(x)	**-18.7**	**-10.6**	**-9.3**	**-7.1**	**2.2**
EV/EBITDA (x)	-18.9	-8.7	-7.2	-5.2	1.7
EV/EBIT (x)	-18.9	-8.7	-7.2	-5.2	1.7
NTA (cps)	2.0	3.1	1.2	0.5	5.4
P/NTA (x)	7.7	4.8	12.7	29.4	2.8
Book Value (cps)	2.0	3.1	1.4	1.9	8.7
Price/Book (x)	7.7	4.8	10.4	7.7	1.7
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 %	0%	-9%	-12%	-14%	44%
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	250	560
USA	-	-	140
Australia/Asia Pacific	20	40	100
Total dose sales	**120**	**290**	**800**
Average revenue per sale A$'000	10	10	12

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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