



Initiating Coverage Report

## Oncosil Medical

Path towards Commercialisation



Chief Research Analyst

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<b>Name:</b>	<b>Oncosil Medical Limited</b>
<b>Country:</b>	<b>Australia</b>
<b>Price:</b>	<b>AUD 0.16</b>
<b>ISIN Code:</b>	<b>AU000000OSL3</b>
<b>Reuters Code:</b>	<b>OSL.AX</b>
<b>Market Cap (AUD m):</b>	<b>67.5</b>
<b>EV (AUD m):</b>	<b>52.5</b>
<b>Cash &amp; cash eq. (AUD m):</b>	<b>15.0*</b>
<b>Shares outstanding (m):</b>	<b>422</b>
<b>Average Daily Volume :</b>	<b>2,078,410</b>
<b>Free float:</b>	<b>100%</b>
<b>52-week Range:</b>	<b>0.07-0.28</b>

AUD million (ending 30/6)	2014A	2015A	2016E
<b>Total Income</b>	0.620	2.802	4.000
<b>Net (Loss)/Profit</b>	(6.865)	(2.879)	(6.100)
<b>Net loss per share (cents)</b>	(1.40)	(0.81)	(1.09)
<b>R&amp;D costs</b>	0.948	1.742	5.000
<b>Cash increase/(decrease)*</b>	(0.772)	(0.216)	10.000*
<b>Cash and marketable sec.</b>	2.739	2.523	12.500

\*) including recent capital raise



## Executive Summary

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- Oncosil Medical (ASX:OSL) is an Australia based Life Sciences company that provides an innovative technology for safer and more effective radiation therapies for difficult to treat cancers like pancreatic cancer and hepatocellular carcinoma (HCC). Its lead product is OncoSil™ for pancreatic cancer. A second indication is HCC. For both indications the company filed for a CE Mark in the EU, which is expected to be granted early 2016.
- OncoSil™ is an implantable device that emits radiation directly into the targeted tumour. Four clinical trials were conducted with positive results on safety and efficacy. Due to the high unmet medical need and the very poor survival rates of both pancreatic and liver cancer, there is a large demand for new therapies to treat these cancer types.
- In July 2015 the company filed the CE Mark Design Dossier for both pancreatic and HCC liver cancer to the Notified Body. In September 2015 it was announced that the Notified Body has scheduled a Fast Track review for OncoSil™, which took place on October 6<sup>th</sup> over a period four days. We expect that the CE Mark will be awarded end of 2016Q1. A CE Mark will facilitate commercialization and sales in large markets other than the EU including Australia, Canada and Singapore. The company also filed for an IDE with the FDA, for which we expect approval towards the end of 2016Q1 as well.
- Both the market for pancreatic cancer and HCC liver cancer are estimated to be USD 1-1.5 billion. The lack of effective treatments that offers significantly improved survival rates provides ample opportunity to be a game changer for the treatment of these cancers. We feel that OncoSil™ therefore has the potential to be a blockbuster (sales > 1 billion) within a few years since the therapy would be useful in other cancers as well.



- Beginning of 2016 the company successfully raised AUD 10 million in an Institutional Placement to finance the commercialization of its lead product candidate Oncosil™. We feel that the company may raise additional capital at a higher price in early 2017 following regulatory success with the CE Mark and FDA IDE filings in Q1 2016. The current cash position after this raise is AUD 15 million.
- There are a number of key milestones to focus on in the next 6-12 months which include: approval of the CE Mark in the EU, start of sales in both the EU and other regions as well (Australia, Canada, Singapore), and the approval of the IDE by the FDA.
- Based on our NPV valuation, we believe that Oncosil Medical is substantially undervalued at the current share price of AUD 0.16. Considering the upcoming CE Mark, OncoSil™'s much higher potential commercial success compared to Sirtex' SIR-Spheres (with total annual sales of more than AUD 176 million) and the high unmet medical need in pancreatic and primary liver cancer, induces us to increase our valuation from our previous estimate of AUD 170-210 million and to calculate a more justified valuation of Oncosil™ of AUD 275-325 million or AUD 0.65-0.80 per share. This represents a substantial upside from the current share price.





## Company Profile & Technology

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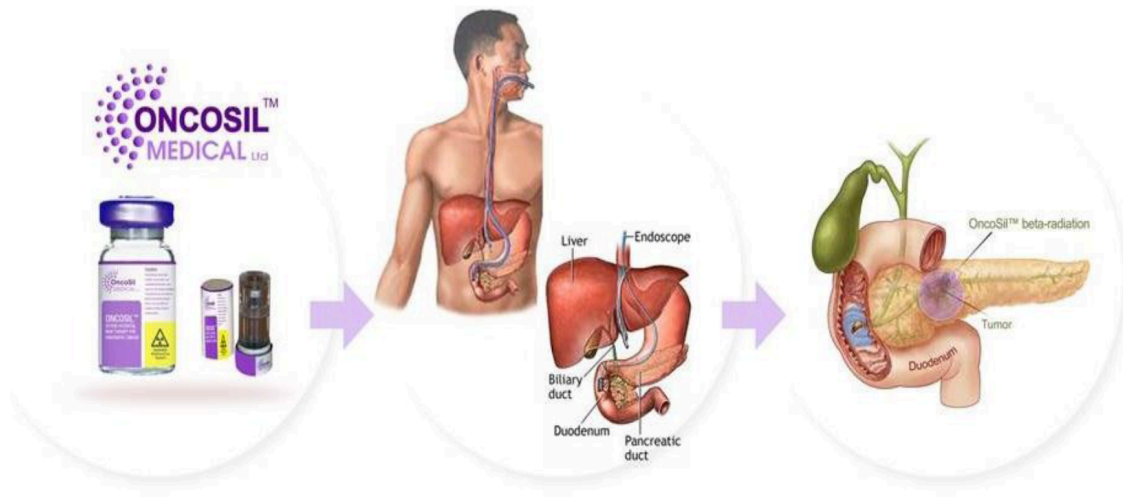
Oncosil Medical (ASX:OSL) is an Australia based Life Sciences company that is developing a novel therapy device that implanted locally emits cancer killing radiation into a tumor, called OncoSil™. The therapy showed favorable results in four Phase II clinical trials in pancreatic and primary liver cancer and the company has recently filed for CE Mark approval that is expected to be announced in early 2016. The CE Mark is required to market and sell OncoSil™ in the EU.

The OncoSil™ therapy is an example of brachytherapy. Brachytherapy is a form of radiotherapy for the treatment of cancer. Most radiotherapy is done externally whereby the patient is placed under a radiation device. However in some cancers like pancreas and liver cancer, internal radiotherapy is much more effective and targets only the tumor without damaging the healthy surrounding tissue. The device consists of a mixture of very small particles of silicon and phosphorus. When the particles are placed in a nuclear reactor for ten days, the phosphorus becomes radioactive. That radioactivity is emitted as beta particles, which only travel about one centimeter through tissues. So healthy tissue is not affected. The radiation that is emitted for up to three months with a half life of 14.3 days. Half-life is crucial in determining whether an isotope will be therapeutically beneficial. Cancer cells are most sensitive to the effects of radiation when they are dividing. At any one point in time, there will only be a small number of cells within a tumour that are dividing. The vast majority is quiescent but will go on to divide over the next days or weeks. It is therefore essential that a therapeutic isotope is active for many days in order to maximise the number of cancer cells that are killed.

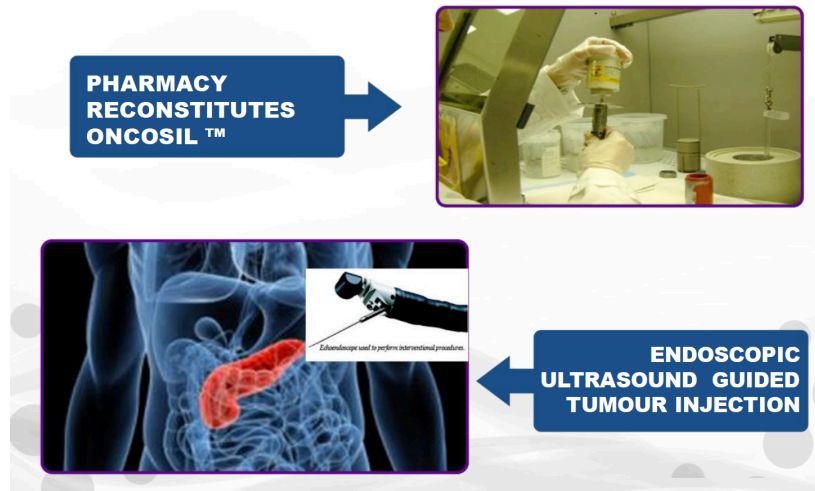
There are also other factors that make P32 an attractive isotope for clinical use. One of the methods for production is to place the stable non-isotopic form of phosphorus in the centre of a nuclear reactor. The neutron flux produced in the reactor converts the inactive P31 to the radioactive P32.

For the production of Oncosil™, the stable form of phosphorus is incorporated into the silicon particles using patented technology that ensures that it is not released. The particles, themselves, are placed within the nuclear reactor and following irradiation they are ready for clinical use. This production technology renders itself to scale-up.

Oncosil Medical has a strategic manufacturing alliance with Eckert&Ziegler, a leader in the manufacture of devices, radiochemicals and radiopharmaceutical precursors used in the treatment of serious diseases. It gives Oncosil access to E&Z's state of the art radioactive manufacturing and storage facility, which enables the company to reduce its cost of goods as well as provide research support.



Source: OncoSil Medical



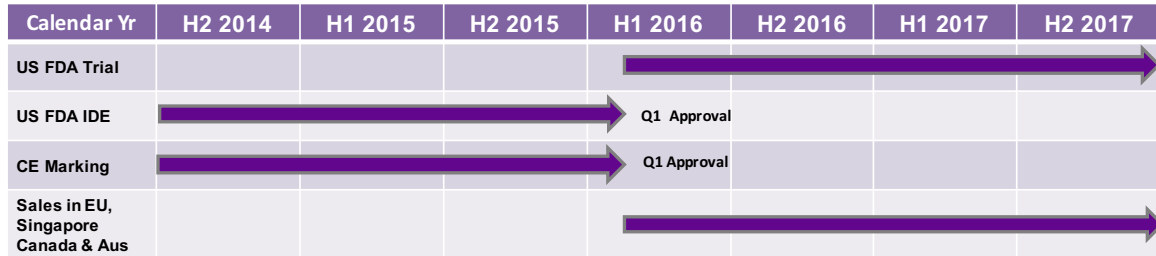
*Source: OncoSil Medical*

For the injection of the device into the pancreatic tumor, the patient is given an anesthetic and the gastroenterologist guides an endoscope down the esophagus, through the stomach and into the first part of the small intestine, which is next to the pancreas. The gastroenterologist uses ultrasound to image the tumor in the pancreas, then extends a needle from the end of the scope into the pancreas and into the middle of the tumor. Then the OncoSil™ suspended in fluid is directly injected into the tumor. This procedure takes around 30 minutes, after which the patient wakes up and can go home.

The OncoSil™ microparticles are very sticky and they remain where they are put in the tumor. The radiation bathes the tumor cells for up to three months killing the tumor cells. After three months, the silicon powder remains and a little non radioactive phosphorus which is taken up by scavenging cells and removed.



## Pipeline: Focus on securing CE-Mark

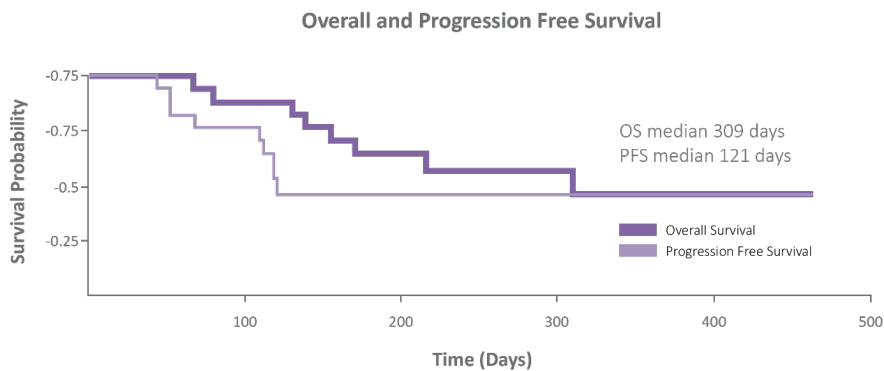


The initial target for OncoSil™ is inoperable pancreatic cancer, as first line treatment in conjunction with standard chemotherapy. Pancreatic cancer continues to pose a major unmet medical need, with 279,000 new cases and 267,000 deaths annually. It is commonly diagnosed late, when it has already spread, and may not be suitable for operative removal. Treatment currently is multiple weekly courses of intravenous gemcitabine chemotherapy for inoperable disease, which only creates on average a five week survival advantage compared to having no treatment administered. Therefore there is a major unmet need for additional therapies that can reduce the tumour burden and increase quality of life in pancreatic cancer patients.

An initial single arm Phase IIa study included 17 locally advanced pancreatic cancer patients. The OncoSil™ particles emitted 100 Gray (Gy) of radiation and were delivered in combination with golden standard gemcitabine. The emitted dose was much higher than what would be possible with external radiotherapy, when only 50-60 Gy is possible. The outcome showed a significant anti-cancer activity with a complete or partial response demonstrated in 81% of patients. The median progression free survival rate of 121 days represented a 71% improvement over gemcitabine alone.

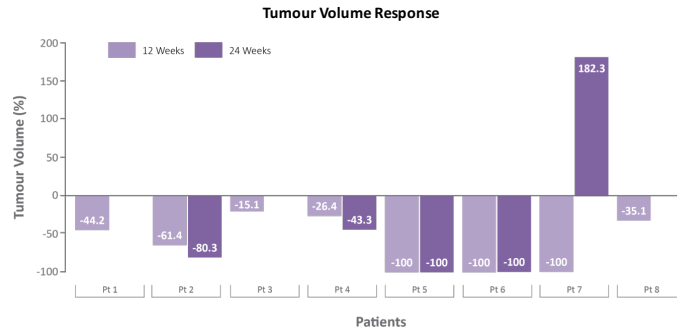


The overall survival rate of 309 days (or 10.2 months) compared to the typical 5.7 months with gemcitabine. Next to this, OncoSil™ was able to reduce abdominal pain of 35%. The company feels that pain reduction would be an approvable endpoint to the device as it would reduce the use of potentially dangerous opioid drugs in pain management and improve quality of life.



Source: OncoSil Medical

In two phase II studies conducted in patients with inoperable primary liver cancer (HCC) OncoSil™ was found to be safe and well tolerated. OncoSil™ monotherapy (no chemotherapy agents used) demonstrated strong evidence of tumor regression & disease control. Reduction in tumor volume was demonstrated in 100% of study patients (8) at 12 weeks post implantation.



Adapted from Goh MD 2007. Results from tumour volume regression at week 12 and week 24 by CT scan post implantation. Patient 1,3 and 8 withdrew before the scan at week 24 not due to an adverse events

With these results, the company filed for a CE Mark in July with the Notified Body. In September it was confirmed that OncoSil has been scheduled for a CE Mark Fast Track review, which took place on October 6<sup>th</sup>. By the end of 2016Q1 we expect the EMA to approve OncoSil™ for the European market. Next to that, the company also has filed an Investigational Device Exemption (IDE) with the US Food and Drug Administration (FDA) for OncoSil™. This is a significant milestone in the development pathway for OncoSil™ in pancreatic cancer and is the first step towards securing FDA commercial approval for OncoSil™ under a Pre-market Approval (PMA). Subject to an IDE being granted, OncoSil Medical will commence a clinical study under the FDA 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. We expect approval of the IDE by the end of 2016Q1 as well.

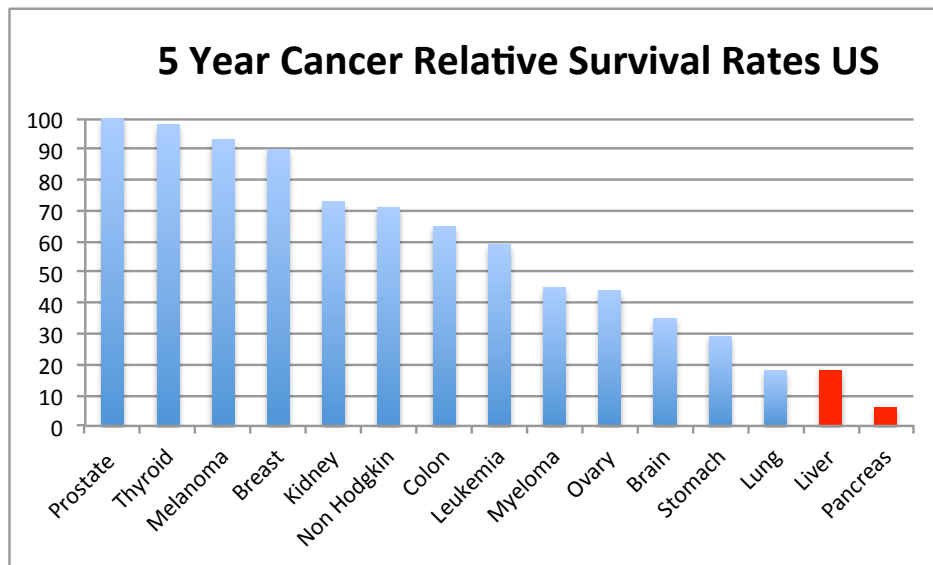
OncoSil™ is classed by regulators as a class III medical device and not a drug. In medical device development, studies are undertaken as pilot and pivotal/registration studies, which mean that medical devices require much less trial work for approval, less funding and have a faster time to approval when compared to drug development.





## Pancreas & Liver cancer: High unmet medical need

Both pancreas and HCC liver cancer both show very poor prognosis for long term survival. Of all the major cancer types, pancreatic cancer has the lowest relative survival rate of only 6%. An average patients typically lives 8-9 months after diagnosis. That survival rate has not changed much over the last two decades. Gold standard therapy has been gemcitabine, which gained FDA approval in 1996. Its peak sales in 2008 were USD 1.7 billion, although it only generated an overall survival rate of 5.7 months. In 2013 Celgene’s drug Abraxane received FDA approval in combination with gemcitabine. The drug increased the median overall survival by a meager 1.8 months to 8.5 months with a combination of gemcitabine and Abraxane from 6.7 months for gemcitabine alone. It already says enough that in almost two decades only two drugs were able to make a small albeit approved improvement in the treatment of pancreatic cancer. That also calls for a different and more sustainable approach to increase overall survival.



Source: American Cancer Society, 2014





Primary liver cancer (Hepatocellular carcinoma, HCC) is the 6<sup>th</sup> most common cancer in the world with 782,000 new cases diagnosed in 2012. Its very poor prognosis makes primary liver cancer the third leading cause of cancer related mortality responsible for approximately 600,000 deaths annually. Hepatocellular carcinoma can be cured by surgery or transplantation.

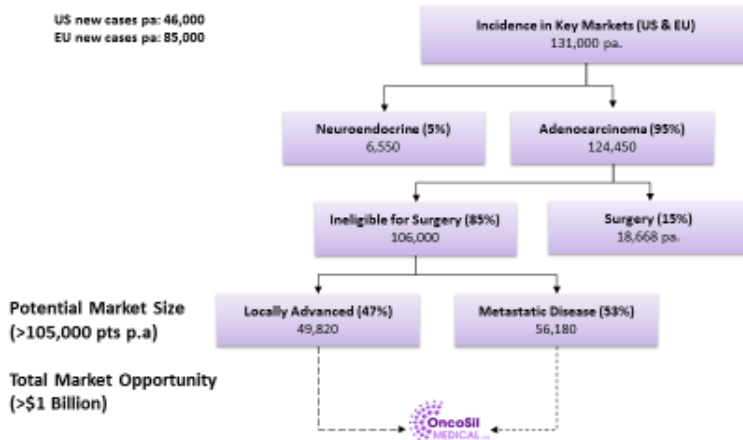
The vast majority of patients with HCC have disease, which is too advanced for surgical intervention. As a consequence survival ranges from a few months to two or more years depending on the liver function at diagnosis and the extent of tumor invasion. The value of the hepatocellular cancer (HCC) market is expected to triple in size to USD 1.4 Billion by 2019

In pancreatic cancer the pool of patients that OncoSil™ targets is high with potential first line use in 75-85% of all patients (see graphs). In the US there will be an estimated 46,000 new cases this year and 85,000 new cases in the EU. Of this group, 85% is ineligible for Surgery and a potential market size for OncoSil™.

## Pancreatic Cancer: Patient Pool assumptions – US & EU



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## Overview Treatment Options in Radio Therapy

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As there are only two chemotherapy drugs on the market that have shown to extend survival marginally, radiation therapy is used in combination of chemotherapy. Radiation therapy is a cancer treatment that uses high-energy radiation, in the form of waves (such as x-rays) or particles (such as protons), to kill cancer cells or prevent them from growing and dividing. Radiation therapy can prevent pancreatic tumors from growing and sometimes shrinks them. There are two main types of radiation therapy, external beam radiation therapy and internal radiation therapy (or brachytherapy).

### *External beam radiation therapy*

This radiation therapy delivers radiation by using a machine outside the body, which directs a beam or multiple beams of radiation through the skin to the tumor or tumor bed. External beam radiation therapy is commonly used in treating pancreatic cancer patients.

### *Internal radiation therapy (brachytherapy)*

Brachytherapy delivers radiation through radioactive material implanted in or near the cancer. This type of radiation therapy is still rarely used in pancreatic cancer patients. OncoSil may well change this dramatically. In addition to standard external beam radiation therapy, the following two methods of planning and delivering external beam radiation are currently used in pancreatic cancer treatment. These specialized methods are able to minimize the amount of radiation delivered to normal tissues and are used when a higher dose of radiation is recommended:



- *Intensity-modulated radiation therapy (IMRT)*

**IMRT** is a type of external beam radiation therapy that delivers focused radiation to the tumor by modulating (varying) the intensity of the radiation beam under precise computer control. By using three-dimensional computer imaging to determine the size, shape and location of the tumor, and by varying the intensity of the radiation dose, IMRT allows a higher dose of radiation to be administered to the tumor while minimizing the amount of radiation delivered to healthy tissue near the pancreas, such as the duodenum (the first portion of the small intestine). This may lead to fewer side effects and allow higher doses of radiation to be delivered safely, compared to standard radiation therapy.

- *Stereotactic body radiation therapy (SBRT)*

**SBRT** is a type of external beam radiation therapy designed to deliver high doses of radiation precisely to small tumors, usually in five or fewer treatments. SBRT uses multiple narrow radiation beams to target small, well-defined areas. In order for SBRT to be delivered safely in pancreatic cancer patients, the tumor must remain motionless or the machine delivering the radiation must be able to adjust for any movement of the tumor, such as during breathing. Patients may be fitted with a customized device to keep the body perfectly still or the treatment machine may have the ability to limit, monitor and adjust for any movement during the treatment. Also, small metallic seeds may be implanted near the tumor before treatment begins to better track the location of the tumor during treatment. CyberKnife® is one type of SBRT. Some studies have suggested that the delivery of high doses of radiation in a few treatments is difficult to accomplish without damaging the intestinal tract.



There is currently no evidence that this type of radiation therapy is better than standard radiation therapy for pancreatic cancer. In fact, one study has shown that stereotactic radiation for pancreatic cancer caused ulcers to develop in the duodenum. There are ongoing studies to determine the appropriate radiation dose and frequency of radiation doses given using SBRT to avoid damaging the duodenum. Therefore, SBRT is still being studied in clinical trials for pancreatic cancer and its usage is only recommended as part of a clinical trial.

### *Proton beam radiation therapy*

This is a type of external beam radiation therapy that uses proton beams rather than x-rays. Protons are charged particles that deposit most of their energy at a very narrow area within the body. Because of this characteristic, proton beam therapy allows a higher, more conformed dose of radiation to be delivered to the tumor, while sparing surrounding healthy tissue. Therefore, it generally causes fewer side effects. Proton therapy is only available at very few centers throughout the US and is being studied in clinical trials for pancreatic cancer.



# SWOT Analysis

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## Strengths

Strong management with extensive relevant technical, commercial and financial expertise

Trials for CE-Mark and FDA IDE demands much less costly clinical trials

Direct product cost savings and work place cost efficiencies

## Weaknesses

Operating losses cumulating year-on-year

Oncosil commercialization requires efforts to educate medical professionals

Competition with established players

## Opportunities

Additional products to leverage off current platform technology, additional markets

High unmet medical need in pancreas and liver cancer

Large growing markets

## Threats

Delay in trials and filing with Oncosil

Delay in roll out in major markets

Failure to sign partnerships in key markets



## Financials

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For the six months ended 31 December 2015, total income amounted to AUD 2.6 million, an increase of 81% compared to the same period last year. This was mainly due to a R&D Tax Incentive of AUD 2.5 million. Expenses for the period totaled to AUD 4.4 million (2014: AUD 3.9 million) including R&D expenses of AUD 2.1 million. Net loss for this period decreased by AUD 0.7 million to AUD 1.8 million.

The company's current cash position after the recent capital raise amounts to AUD 15 million. According to the company this should be sufficient to finance the initial commercialization of Oncosil radiation treatment for cancer. However, we believe that the company will need to raise additional capital to finance the set up of a sales force in Europe and Asia-Pacific. For the US we think that the company will work together with a sales partner.

For 2016FY we expect the first revenues from the first doses Oncosil sold in Europe and reaching USD 0.5-0.8 million at a dosage price of USD 10,000. For the US market we calculate a higher price of USD 15,000 per dosage. These prices are in line with the first US sales is expected in 2018, which we calculate to be within the range of USD 0.3-0.5 million. Cost of goods sold (COGS) is expected to gradually reduce to 20-25% in the years after 2017. Most important costs are associated with selling and marketing, which we expect to exceed total revenues in 2016-2018. In 2016, we expect SG&A as a percentage of revenues will be 200%, and decrease below 50% after 2019. We expect the company to reach near break even in 2020. For the longer term we estimate the company will reach an EBIT margin of 50-55%. In our valuation model we work with an average EBIT margin of 40% that also includes payment of an 8% sales based royalty to pSiVida. This is part of a license agreement that Oncosil Medical has in place since 2012. We also expect that Oncosil Medical will seek a sales partner for the US market.



## Profit & Loss Statement

AUD mln	2014A	2015A	2016E	2017E
Revenues	0.0	0.0	1.000	3.220
COGS	0.0	0.0	0.700	1.720
Gross Profit	-	-	0.300	1.500
Other Income	0.620	2.802	3.000	3.000
R&D Costs	(0.948)	(1.742)	(5.000)	(10.000)
Other	(6.534)	(3.938)	(3.000)	(5.000)
SG&A	0	0	(6.100)	(3.000)
Operating Profit/(Loss)	(6,865)	(2.879)	(00)	(13.500)
Income Taxes	0	0	0	0
Net Profit/(Loss)	(6.865)	(2.879)	(6.100)	(13.500)

## Consolidated statement of cash flows

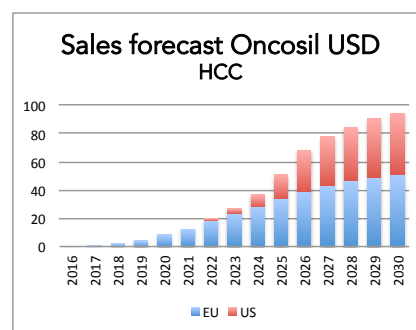
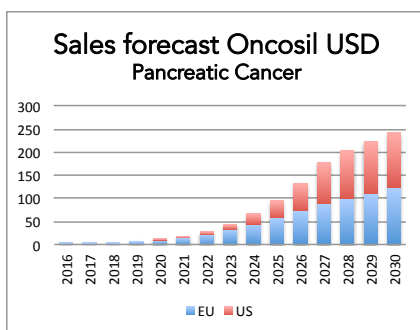
AUD mln	Dec 31 <sup>st</sup> 2014A (6 months)	Dec 31 <sup>st</sup> 2015A (6 months)	June 30 <sup>th</sup> 2016E (12 months)
Cashflow from operating activities	(0.767)	(1.270)	(8.000)
Cash flow from investing activities	(0.391)	(0.02)	(0.0)
Cash flow from financing activities	-	1.0	15.000
Cash and cash equivalents at beginning of the period	2.739	2.523	2.522.
Net change in cash and cash equivalents	(1.137)	(0.255)	7.000





## Valuation

Based on our NPV valuation, we believe that Oncosil Medical is substantially undervalued at the current share price of AUD 0.16. Considering the upcoming CE Mark, OncoSil™ much higher potential commercial success compared to Sirtex' SIR-Spheres (with total annual sales of more than USD 110 million) and the high unmet medical need in pancreatic and primary liver cancer, we arrive at a value of AUD 284 million for Oncosil Medical using a risk adjusted Net present value based on future income from Oncosil™ for pancreatic cancer and HCC. We model sales and cash flow up until 2030. We assume European launch of OncoSil™ in 2016Q2 and the US launch in 2020. Our forecast includes sales of Oncosil™ for Pancreatic Cancer and HCC, reaching revenues by 2030 of USD 250 million and USD 90 million respectively, and reaching market shares in the European and US of 10-12%. Based on figures of the American Cancer Society and the European Cancer Observatory, the number of new patients with pancreatic cancer are estimated to be 46,000 and 85,000 per year respectively. 85% of these patients are inoperable and can potentially be treated with Oncosil™. In our valuation model for Oncosil Medical, we do not include additional indications as well as potential revenues outside of the US and Europe. Additional revenues from Asia offer additional upside potential. **Applying a WACC of 10%, we value Oncosil Medical at AUD 0.70 per share.**



Source: Van Leeuwenhoek Institute Inc



## Sales forecast and valuation Oncosil for Pancreatic Cancer (USD)

Year	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Market share EU	0.1%	0.2%	0.4%	0.8%	1.3%	2.0%	3.0%	4.5%	6.0%	8.0%	10.0%	12.0%	13.5%	15.0%	17.0%
Market share US	0.0%	0.0%	0.0%	0.0%	0.2%	0.5%	1.0%	1.8%	3.8%	6.0%	10.0%	15.0%	17.5%	19.0%	20.0%
Dosages EU	72	147	293	587	953	1467	2200	3300	4400	5867	7333	8800	9900	11000	12283
Dosages US	0.0	0.0	0	0	79	198	397	714	1508	2381	3969	5953	6945	7540	7937
Revenues EU	0.7	1.5	2.9	5.9	9.5	14.7	22.0	33.0	44.0	58.7	73.3	88.0	99.0	110.0	122.8
Revenues US	0.0	0.0	0.0	0.0	1.2	3.0	6.0	10.7	22.6	35.7	59.5	89.3	104.2	113.1	119.1
Total Revenues	0.7	1.5	2.9	5.9	10.7	17.6	28.0	43.7	66.6	94.4	132.9	177.3	203.2	223.1	241.9
EBIT 40%	0.3	0.5	1.0	2.1	3.8	6.2	9.8	15.3	23.3	33.0	46.5	62.1	71.1	78.1	84.7
WACC 10%	0.90	0.81	0.73	0.66	0.59	0.53	0.48	0.43	0.39	0.35	0.32	0.29	0.26	0.23	0.21
Disc. NPV (million)	0.2	0.4	0.8	1.4	2.2	3.3	4.7	6.6	9.1	11.6	14.8	17.7	18.3	18.1	17.7
<b>Total NPV (million)</b>	<b>120</b>														
<b>Value per share (AUD)*</b>	<b>0.42</b>														
*) USD/AUD = 1.43															

## Sales forecast and valuation Oncosil for HCC (USD)

Year	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
Market share EU	0.1%	0.2%	0.4%	0.8%	1.6%	2.4%	3.6%	4.6%	5.5%	6.6%	7.6%	8.5%	9.1%	9.6%	10.0%
Market share US	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.4%	0.8%	2.0%	4.0%	6.8%	8.0%	8.8%	9.6%	10.0%
Dosages EU	0	102	205	410	819	1229	1843	2355	2816	3379	3891	4352	4659	4915	5120
Dosages US	0	0	0	0	0	0	115	230	576	1152	1958.4	2304	2534	2764	2880
Revenues EU	0.0	1.0	2.0	4.1	8.2	12.3	18.4	23.6	28.2	33.8	38.9	43.5	46.6	49.2	51.2
Revenues US				0.0	0.0	0.0	1.7	3.5	8.6	17.3	29.4	34.6	38.0	41.5	43.2
Total Revenues	0.0	1.0	2.0	4.1	8.2	12.3	20.2	27.0	36.8	51.1	68.3	78.1	84.6	90.6	94.4
EBIT 40%	0.0	0.4	0.8	1.6	3.3	4.9	8.1	10.8	14.7	20.4	27.3	31.2	33.8	36.2	37.8
WACC 10%	0.9	0.8	0.7	0.7	0.6	0.5	0.5	0.4	0.4	0.4	0.3	0.3	0.3	0.2	0.2
Disc. NPV (million)		0.3	0.6	1.1	2.0	2.8	4.1	5.0	6.2	7.9	9.6	10.0	9.8	9.5	9.0
<b>Total NPV (million)</b>	<b>78</b>														
<b>Value per share (AUD)*</b>	<b>0.28</b>														
*) USD/AUD = 1.43															



## Management Capabilities

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Seasoned innovators in healthcare are rebuilding Oncosil Medical. The company is led by an experienced and partly renewed Board and management team, which has been responsible for Oncosil moving forward and for the recent filings of Oncosil and has a successful track record of developing, protecting and commercializing innovative scientific products and processes. Oncosil has been investing in developing a team of experts that have a focus on patient outcomes and can deliver results. Its board and senior management team are highly experienced in the development and commercialization of therapies in oncology.

### Management Team

#### **Daniel Kenny, Chief Executive Officer**

Daniel Kenny joined OncoSil Medical in January 2015 with almost 30 years' experience in the Global Pharmaceutical and Medical Device industry. Daniel is an accomplished and proven biopharmaceutical business leader and in his career he has developed and successfully driven business with industry leaders such as Roche, Allergan and Baxter working in Australia, EMEA and the US. Prior to joining OncoSil Medical, Daniel held the position of Chief Commercial Officer at ABIVAX a Paris based global biopharmaceutical company specializing in the development of novel vaccines and anti-virals. At Baxter Daniel served as Global Franchise Head Vaccines overseeing all Franchise Operations. Before this role, Daniel served as Vice President Baxter BioScience, EMEA with responsibility for all marketing and key business programs in support of regional sales exceeding USD 1.9 billion. Daniel also served with Roche as Global LifeCycle Leader for Roaccutane, a product generating sales in excess of CHF 1.1 billion (2002) assuming responsibility for all global strategic marketing and business development activities. Prior to this role he was International Medical Manager and Medical Science and Safety Team leader responsible for post NDA clinical development strategy and critical issue work ups for regulatory authorities.



## Tom Milicevic, Chief Financial Officer

Mr Milicevic is a vastly experienced commercial, financial and management accountant with more than 20 years experience in a career which includes a number of major Australian and international public companies. He has specific financial expertise in medical device and biotech companies and his recent appointment represents a pivotal hire for OncoSil as it transitions from a development focus to the commercialisation of its OncoSil radiation treatment. Prior to joining OncoSil Medical, Tom was CEO and CFO of orthopaedic medical device company Allegra Orthopaedics (ASX:AMT) and successfully led the company through its IPO and ASX listing in 2007. Mr Milicevic was also CFO for Babcock & Brown Residential Land Partners, an ASX listed fund, where he was the financial lead on the stapled security's AUD 175 million IPO. His previous roles include CFO and Company Secretary with ASX listed biotech company Avantogen, until it relocated to the US and senior accounting roles with Cochlear, Boral and Smorgon Steel Group.

## Dr Ashish Soman, Chief Medical Officer

Dr Soman is a highly experienced medical professional and pharmaceutical industry executive with more than 24 years experience, and his appointment is a key, strategic addition to OncoSil Medical's executive leadership team. Ashish plays a vital role in the company's regulatory approvals process, including the CE Mark and the US FDA IDE, and commercialisation of the OncoSil radiation therapy. His previous roles include Country Medical Director, Australia for major pharmaceutical company AstraZeneca, where he managed a team of 30 employees spanning medical affairs, medical information and publications, compliance and patient safety. Prior to that he was Medical Director Cardiovascular & Diabetes for AstraZeneca Australia. Dr Soman has also previously held roles with Sanofi-aventis Australia-New Zealand and Roche in the UK. He commenced his career as a practising hospital clinician with the UK National Health Service.



## David James, Global Head of Manufacturing Operations

Mr James is a highly experienced pharmaceutical manufacturing operations executive with more than 25 years' experience in this field, including six years with leading cancer treatment company Sirtex Medical (ASX: SRX ) as Global Operations Manager. During his time at Sirtex he was responsible for managing the global operations team including production, logistics, customer service and engineering. This included responsibility for the design, construction and commissioning of Sirtex's first in-house manufacturing plant in Wilmington DC, in the US. David has a Masters in Business and Technology from the University of New South Wales, and a Bachelor of Science from the University of Newcastle. David is a Chartered Chemist with the Royal Australian Chemical Institute.

## Charles Rowland, President of US Operations

Mr. Rowland was previously President of Sirtex Medical US from 2002 to 2006, and is a highly experienced healthcare executive with a successful record of commercialising medical devices and growing medical device companies in the diagnostics, cardiac patient management and liver cancer markets. In his role with Oncosil Medical Mr. Rowland will be responsible for developing and executing the Company's US Business plan and will be the Company's official representative with the US FDA as it works towards US licensure for its lead product candidate, the OncoSil™ localised radiation treatment for cancer. Mr. Rowland will work with the Company's medical and regulatory team and with Key Opinion Leaders as the Company moves forward with the introduction of OncoSil™ into the US market. During his tenure with Sirtex Medical Mr. Rowland was responsible for establishing the team that launched and commercialised SIR-Spheres in the US market. Under his management, Sirtex's US business grew to almost \$20 million, accounting for over 80% of Sirtex Medical's global revenues at the time. Mr. Rowland served on the Sirtex board of directors from 2003 to 2006.



## Board of Directors

### **Roger Aston, Chairman**

Dr. Roger Aston, BSc (Hons) PhD serves as the Executive Chairman of OncoSil Medical. He has had extensive experience on boards of many pharmaceutical companies, and has been CEO of Pitney Pharmaceuticals Ltd, PSIMEDICA, PSIONCOLOGY PTE LTD, Peptech and Cambridge Antibody Technology. In 2001, Dr Aston co-founded pSivida Limited. He served as the Chief Executive Officer of Hospira Australia Pty Ltd, and as Chief Executive Officer of Mayne Pharma Group Limited until February 15, 2012. During his career, 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, global licensing agreements, fundraising through private placements, and a network of contacts within the pharmaceutical, banking and stock broking sectors. Dr Aston is both a scientist and seasoned biotechnology entrepreneur, with a successful track record in both fields. He currently has several executive and non-executive board positions with prominent biotechnology companies.

### **Martin Rogers, Non-Executive Director**

Martin Rogers is a successful startup investor and company director. Mr Rogers has Chemical Engineering and Science degrees and has a depth of experience in incubating companies and publicly listed organisations. Mr Rogers has experience in all aspects of financial, strategic and operational management and has helped raise over \$100m cash equity. Mr Rogers has been both an investor and senior executive in a private funded advisory business in the science and biotechnology sectors, where he was instrumental in significantly increasing the value of those investments. Mr Rogers also holds a number of not-for-profit roles.





### **Dr Chris Roberts, Non Executive Director**

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. Dr Roberts has forged a long and successful career in the medical device sector. He was Chief Executive Officer/President of Cochlear Limited (ASX: COH) from February 2004 to August 2015. Cochlear is the global market leader in implantable devices, such as cochlear implants, for the hearing impaired. Dr Roberts was primarily responsible for the significant increase in Cochlear Limited's sales from \$348m in 2005 to \$926m in 2015. Dr Roberts was also previously Chairman of Sirtex Medical Ltd (ASX: SRX), from March 2000 to December 2002, and was Executive Vice-President of global sleep disorder treatment company ResMed Inc (NYSE: RMD, ASX: RMD) from 1992 to 2004. He is currently a Non-executive Director of ResMed Inc. He is a member of the Board of Governors of the Centenary Institute of Cancer Medicine and Cell Biology, and is an Honorary Fellow of the Australian Institute of Business and Economics at the University of Queensland. Dr Roberts holds a BE (Honours) in Chemical Engineering (UNSW), an MBA (Macq) and a PhD (UNSW) and was awarded Honorary Doctor of Science degrees from Macquarie University and the University of NSW. He is a Fellow of the Academy of Technological Sciences and Engineering (FTSE), Fellow of the Australian Institute of Company Directors (FAICD) and Honorary Fellow of The Institution of Engineers Australia (FIEAust).





## Upcoming Milestones

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There are a number of key milestones to focus on in the next 1-6 months.

### 2016H1

- Announcement CE-Mark approval in the EU
- Commencement of sales in EU, Canada, Australia, New Zealand and Singapore
- Approval US FDA IDE
- Commencement of OncoPac-1 Study in pancreatic cancer



## Competitive Landscape

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During examination of comparable companies we looked at medical device companies that have radiology therapy products in cancer, preferably liver and pancreatic cancers. Companies like Sirtex, Oncura, Isoray, Elekta and BTG.

### *Sirtex*

Sirtex Medical Limited is an Australia-based healthcare and medical device company, which manufactures and distributes liver cancer treatments utilizing small particle technology. The Company's segments are based on the regional markets it operates, which include Asia Pacific, The Americas, and Europe, the Middle East and Africa (EMEA). The Company's lead product is a focused radiation therapy known as SIR-Spheres Y-90 resin microspheres, which is a radioactive treatment for liver cancer. The treatment is called Selective Internal Radiation Therapy (SIRT) and consists of a minimally invasive surgical procedure performed by an interventional radiologist. The SIR-Spheres microspheres lodge in the small blood vessels of the tumor where they destroy it from the inside over a short period while sparing the surrounding healthy tissue. It is available in more than 40 countries and over 900 hospitals. The Company has manufacturing and operations in the United States, Germany and Singapore.

### *Isoray*

Isoray develops, manufactures and sells isotope-based medical products and devices for the treatment of cancer and other malignant diseases. The Company is engaged in treatment for all solid tumors using Cesium-131. Cesium-131 is a radioactive isotope that can be produced by the neutron bombardment of Barium-130 (Ba-130). The brachytherapy seed form of Cesium-131 may be used in surface, interstitial and intracavity applications for tumors with known radio sensitivity. The Company's product candidate is Proxcelan Cesium-131. The Company markets the Proxcelan



Cesium-131 brachytherapy seed for the treatment of prostate cancer; brain cancer; lung cancer; head and neck cancers; gynecological cancer: pelvic/abdominal cancer; colorectal cancer, and ocular melanoma. To produce the Proxcelan seed, the purified Cesium-131 isotope is adsorbed onto a ceramic core containing a gold X-ray marker. The Company also markets the GliaSite RTS for the treatment of brain cancer, such as primary and recurrent gliomas and metastatic brain tumors. GliaSite RTS is a cleared balloon catheter device. The main components included in the GliaSite RTS are the GliaSite Catheter Tray, GliaSite Access Tray, Iotrex Solidifier and either Iotrex or Cesitrex as the radiotherapy solution. The catheter tray includes a GliaSite RTS catheter, two non-coring needles, and two right anchoring clips. Cesitrex is the liquid form of Cesium-131 and can be used in place of Iotrex, the liquid form of Iodine-125, in the Company's GliaSite RTS.

### Accuray

Accuray is a radiation oncology company. The Company develops, manufactures, sells and supports treatment solutions. Its suite of products includes the CyberKnife Systems and the TomoTherapy Systems. Its technologies, the CyberKnife and TomoTherapy Systems, are designed to deliver treatments, including radiosurgery, stereotactic body radiation therapy, intensity modulated radiation therapy (IMRT), image guided radiation therapy (IGRT) and adaptive radiation therapy. Its principal radiosurgery products, the CyberKnife Systems are robotic full-body radiosurgery system designed to treat tumors anywhere in the body non-invasively, which include the CyberKnife M6 Series with configuration options of fixed collimators plus iris variable aperture collimator (FI), fixed collimators plus the InCise MLC (FM) and fixed collimators plus iris variable aperture collimator and the InCise MLC (FIM). The TomoTherapy Systems include the TomoTherapy H Series with configuration options of TomoH, TomoHD and TomoHDA. The Company has operations in Americas, Europe, Middle East, India, Africa and Japan. The CyberKnife Systems are robotic systems that deliver stereotactic radiosurgery (SRS) and stereotactic body radiation therapy (SBRT) and are used to treat multiple types of cancer and tumors throughout the body. The CyberKnife Systems track, detect and correct tumor and patient movement in real-time during the



procedure. Treatment with the CyberKnife Systems requires no anesthesia, and can be performed in one to five staged treatment sessions on an outpatient basis. The CyberKnife Systems deliver treatments for intra- and extra-cranial disease sites throughout the body, including prostate, lung, brain, spine, liver, pancreas and kidney. The CyberKnife M6 Series System is available with the InCise multi-leaf collimator (InCise MLC), which is available on a robotic platform. Its configurations of CyberKnife Systems include the CyberKnife M6 Series with configurations of FI, FM and FIM and CyberKnife VSI System. The CyberKnife M6 Series system includes disease-specific tracking and treatment delivery solutions for brain, spine, lung and prostate tumors, treatment speed improvements and options to configure the treatment room. The CyberKnife VSI System comes with fixed collimators or an optional Iris collimator.

### *BTG plc*

BTG plc is a specialist healthcare company. The Company operates in three business segments: Interventional Medicine (IM) (oncology, vascular and pulmonology products), Specialty Pharmaceuticals (antidote products) and Licensing (royalties from licensed assets). The Company's Interventional Medicine segment offers a portfolio of interventional medicine products that are designed to advance the treatment of liver tumors, advanced emphysema, severe blood clots and varicose veins. The Company's Specialty Pharmaceuticals segment offers a portfolio of antidote products that alleviate toxicity and treat rare conditions. The Company's Licensing segment receives royalties relating to the sales of products that are subject to intellectual property and license agreements between the Company and various partners. The Company's subsidiaries include BTG International (Holdings) Ltd, Provensis Ltd, BTG International Ltd and BTG Employee Share Schemes Ltd, among others.



*Analyst: Marcel Wijma MSc*

*Marcel Wijma, Chief Research Officer and managing partner, has a longstanding history in financial biotech research. After selling Van Leeuwenhoek Research (VLR) to SNS Securities in 2006, he established an award winning analyst team in biotech/life sciences at SNS Securities. In 2009, Marcel was awarded by Financial Times/Starmine as being one of the Top-3 biotech analysts in Europe. Later that year, Marcel purchased VLR from SNS Securities after which the company was reconstituted. At VLR, he leads the professional VLR research organisation, which is augmented by selected external financial researchers with a specialisation in Life Sciences. Mr. Wijma has a Masters degree in Financial Economics from Erasmus University in Rotterdam.*

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