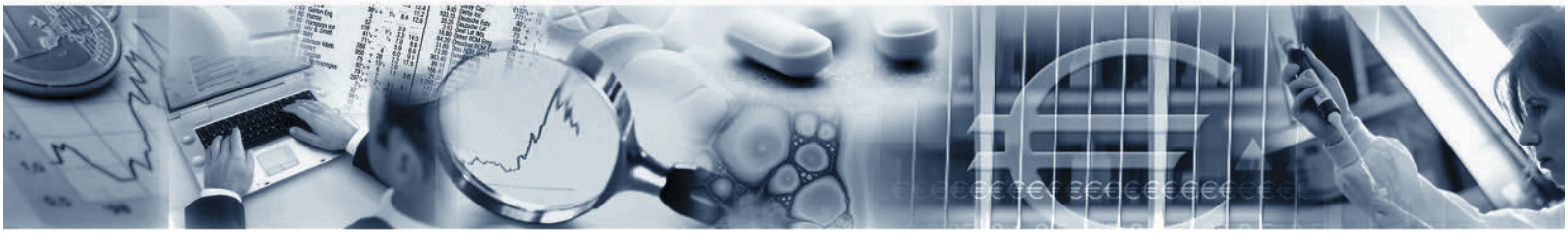

Research Note

Oncosil Medical

CE-Mark imminent

Chief Research Analyst

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Name:	**Oncosil Medical Limited**
Country:	**Australia**
Price:	**AUD 0.145**
ISIN Code:	**AU000000OSL3**
Reuters Code:	**OSL.AX**
Market Cap (AUD m):	**51.6**
EV (AUD m):	**45.5**
Cash & cash eq. (AUD m):	**6.1**
Shares outstanding (m):	**355.4**
Average Daily Volume (m):	**1.200**
Free float:	**100%**
52-week Range:	**0.07-0.16**

AUD million (ending 30/6)	2014A	2015A	2016E
Total Income	0.620	2.802	4.000
Net (Loss)/Profit	(6.865)	(2.879)	(2.000)
Net loss per share (cents)	(1.40)	(0.81)	(0.56)
R&D costs	0.948	1.742	1.500
Cash increase/(decrease)	(0.772)	(0.216)	10.000
Cash and marketable sec.	2.739	2.523	12.500

Executive Summary

- 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.

- 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 the company filed the CE Mark Design Dossier for both pancreatic and HCC liver cancer to the Notified Body. On September 6th it was announced that the Notified Body has scheduled a Fast Track review for OncoSil™, which will take place on October 6th and will be conducted over four days. A CE Mark will facilitate commercialization and sales in large markets other than the EU including Australia, Canada and Singapore. The company expects to file for an IDE with the FDA in 2016Q4.

- 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.

- 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.

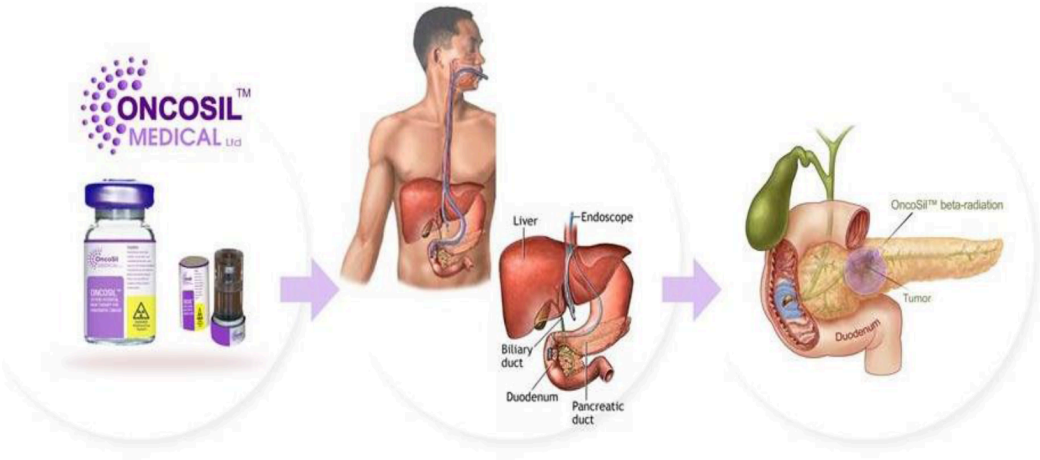
- Based on our NPV valuation, we believe that Oncosil Medical is substantially undervalued at the current share price of AUD 0.145. Considering the upcoming CE Mark, OncoSil™ much higher potential commercial success compared to Sirtex' SIR-Spheres (with total annual sales of more than USD 110 million) and the high unmet medical need in pancreatic and primary liver cancer, induces us to calculate a more justified valuation of Oncosil of AUD 175-210 million or AUD 0.50-0.60 per share. This represents a substantial upside from the current share price.

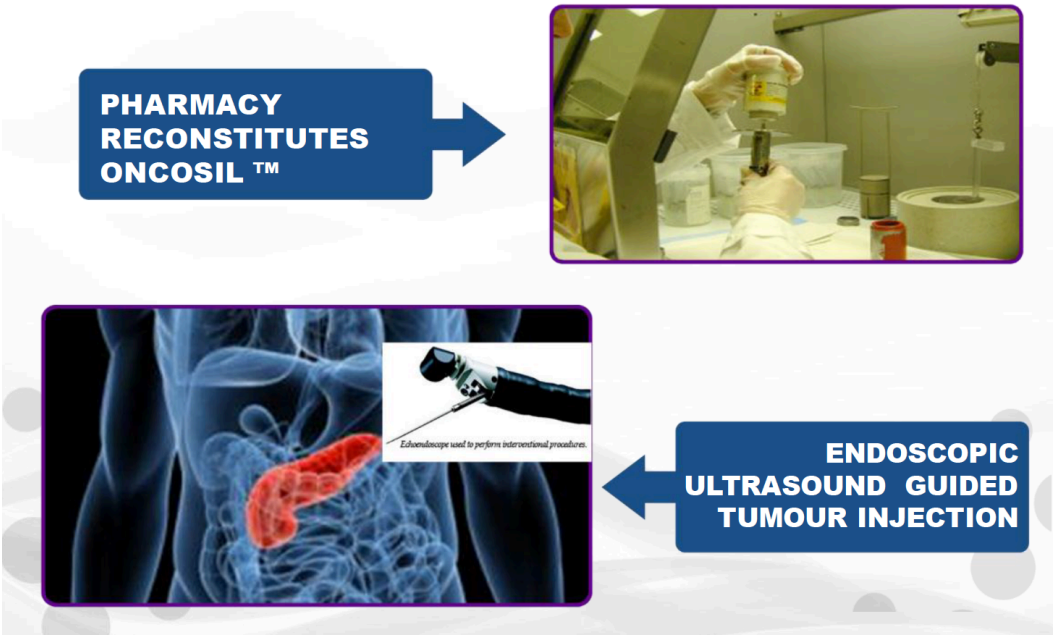
Company Profile & Technology

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 November. 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.

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 reduces its cost of goods as well as provide research support.





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 where 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 82% 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.

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.

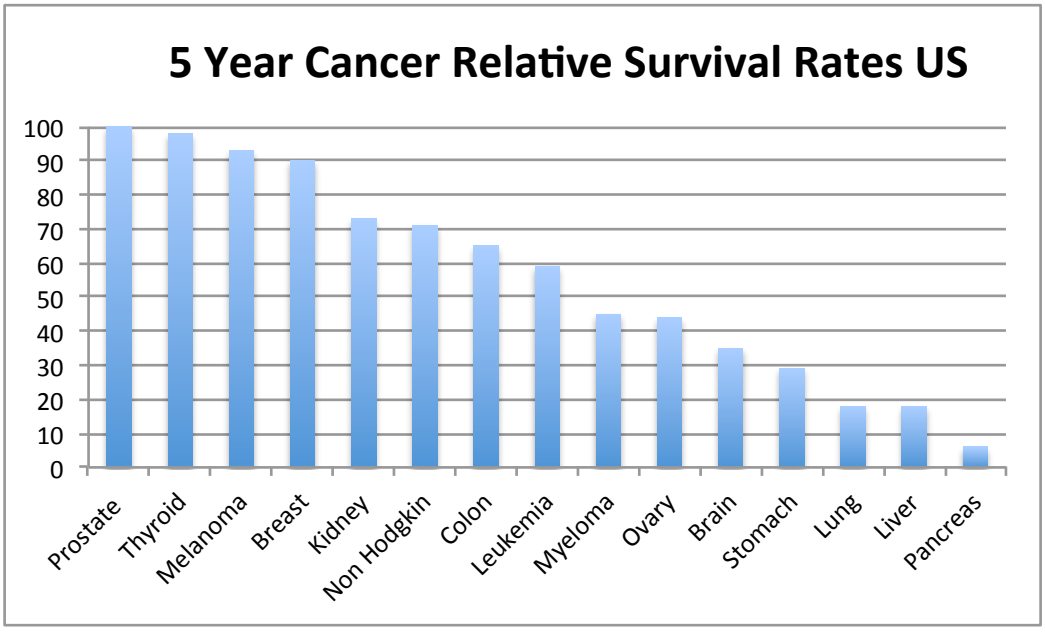
With these results, the company filed for a CE Mark in July with the Notified Body. In September it was confirmed that OncoSil™ has been scheduled for a CE Mark Fast Track review, which will take place on October 6th.

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.

Next to the CE Mark, the company intends to secure a FDA Investigational Device Exemption (IDE) in pancreatic cancer. For that the company is preparing to commence a global, multi-center, randomized study in pancreatic cancer. This study, OncoPac-1 will evaluate the safety and effectiveness of OncoSil™ given in combination with standard of care chemotherapy. Data collected from this study will be used to support US FDA regulatory approval

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.

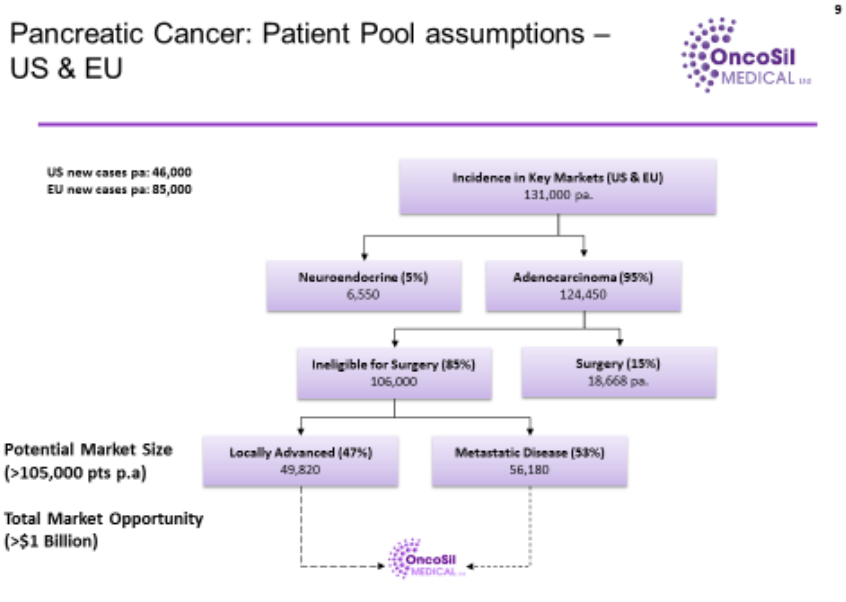


Source: American Cancer Society, 2014

Primary liver cancer (Hepatocellular carcinoma, HCC) is the 6th 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™



Upcoming Milestones

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

2015H2/2016H1

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

Valuation

Based on our NPV valuation, we believe that Oncosil Medical is substantially undervalued at the current share price of AUD 0.14. 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, induces us to calculate a more justified valuation of Oncosil of AUD 175-210 million or AUD 0.50-0.60 per share.

Our WACC was 18% and we assumed a 80% probability that OncoSil™ will receive the CE Mark We assume European launch of OncoSil in 2016Q1 and in the US three years later. We believe that OncoSil™ can achieve peak sales of USD 200 million in Europe and USD 120 million in the US in pancreatic cancer, whereas for HCC liver cancer we estimate USD 100 million and USD 60 million. This assumes that the therapy confers a medically meaningful survival benefit is priced at USD 12,000 per course of treatment and gains 20-25% market penetration within 10 years. This is based on the number of new patients with pancreatic cancer in the US and Europe that is estimated to be 131,000 each year (see also graph on page 11).

Analyst: Marcel Wijma MSc

Marcel Wijma, Chief Research Officer and managing partner, has a longstanding history in financial biotech research. After selling Van Leeuwenhoeck 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.