

OncoSil Medical Ltd

On the road to commercialisation

OncoSil Medical (ASX:OSL) is medical device company developing and commercialising a novel form of brachytherapy for the treatment of pancreatic and bile duct cancers. OSL's lead product Oncosil™ is a targeted radioactive isotope (Phosphorus-32), implanted directly into a patient's pancreatic tumours via an endoscopic ultrasound. This treatment delivers a more concentrated and localised beta radiation relative to external beam radiation in a condition that has poor prognosis upon diagnosis (~5% survival rate 5-years post diagnosis). Recent trial results suggest an excellent safety profile, a Prolonged Overall Survival (OS) of 16.1 months and excellent Local Disease Control (LDCR) of 90.5% among other findings. In April 2020, the company received CE Marking which allows for the Oncosil™ device to be marketed and sold in Europe/UK. OncoSil wasted no time raising capital to and is now fully funded to commercially launch in Europe. Despite the disruptions caused by COVID-19, the company is tracking towards first revenues later this year. The company has also received regulatory clearance in New Zealand, Singapore and Malaysia, and is awaiting outcomes in Australia and Hong Kong. In the US, the company has a dual pathway to market, through the indications of locally advanced pancreatic cancer and bile duct cancer. In terms of bile duct cancer, the company submitted a Humanitarian Device Exemption application and is awaiting the outcome from the FDA. In terms of LAPC, the company continues to work closely with the FDA leveraging its breakthrough designation to expedite work and design clinical trials. OSL ended FY20 with a cash balance of \$21m, placing it in a strong position to advance commercialisation plans.

Business model

The business model of OSL is to transform the prognosis of pancreatic cancer through successfully commercialising its Oncosil™ device globally. In April 2020, the company was granted CE Mark for the treatment of locally advanced pancreatic cancer in combination with chemotherapy, allowing the device to be marketed and sold in Europe and UK. In Asia, OncoSil has received the necessary approvals in Singapore, New Zealand and Malaysia; and is awaiting the outcomes in Australia and Hong Kong. Approval in the US will require a pivotal trial, with discussions with the FDA ongoing to define the clinical trial design and endpoints. Being a platform technology, OncoSil is concurrently entering the US market through the indication of bile duct cancer. OncoSil submitted a Humanitarian Device Exemption application in July 2020 and is expecting a regulatory decision later this year.

Recent company commentary

OSL raised \$19m in equity capital in May 2020 at \$0.09/share to fund the commercialisation of Oncosil in the UK/Europe, accelerate US commercialisation of bile duct cancer and allow commencement of clinical trials in the treatment of pancreatic cancer in the US. As a result, OSL finished FY20 with a cash balance of \$21m. The company is currently non-revenue generating but recorded \$2.8m in R&D tax rebates and government grants in FY20. The company reported an adjusted operating loss (excluding share-based payments) of \$6.5m and operating cash outflow of \$4.4m. The company expects to be revenue generating in FY21 having achieved regulatory clearance to sell its device in Europe, UK and parts of Asia in FY20.

Commercialisation at odds with most peers

While direct peers are difficult to establish in biotech companies, given varying stages of trial progress, various levels of funding and wildly fluctuating estimates of the Total Addressable Markets (TAM), OSL is one of the few listed Australian biotechs at commercialisation.

Medical Devices

4 September 2020

Share details

ASX Code	OSL
Share price (3-Sep)	\$0.14
Market Capitalisation	\$95.3M
Shares on issue	828.6M
Net cash at 30/06/2020	\$21M
Free float	82.2%

Share performance (12 months)



Upside Case

- Commercial sales success
- Regulatory progress in the US
- Positive clinical trial outcomes

Downside Case

- Lower than expected sales of Oncosil
- Regulatory delays
- Access to funding

Catalysts/upcoming events

- First commercial sales of Oncosil™ (2QFY21)
- US pivotal trial design (2HFY21)

Comparable companies (Aust/NZ)

Kazia Therapeutics (ASX:KZA), Actinogen Medical (ASX:ACW)

Top 5 shareholders

Regal Funds Management Pty Ltd	4.52%
Lumyna Investments Ltd	3.62%
Webinvest Pty Ltd	2.98%
Daniel Kenny (CEO)	2.46%
Bannaby Investments Pty Ltd	2.27%

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FINANCIAL SERVICES GUIDE

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