



## Investor Update

*Advancing pancreatic cancer treatment  
Transforming the prognosis*

February 2021





Transforming the prognosis

***OncoSil will be a market leader in pancreatic cancer therapy, aimed at extending the length and quality of life of patients***

# Introduction to Nigel Lange



- 35+ years' experience in pharmaceutical and medical device industries
- Served as Europe CEO, Group COO and Interim Group CEO of Sirtex Medical, a global leader in brachytherapy treatment for liver cancer
- Clear understanding of pathway to successful device launch and uptake
- Extensive experience launching SIR-Spheres™ and TheraSphere™ technologies in US and Europe
- Familiar with Australian market and business environment
- Proven leadership in ASX-listed company<sup>1</sup>

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***I am delighted to be appointed as CEO as I firmly believe in the technology and the critical role it plays in this area of unmet clinical need.***

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# An exciting and attractive outlook for OncoSil

## PanCO study success

- PanCO was a single-arm study designed to obtain regulatory approval
- The study was successful, with CE Marking approval granted in April 2020

## Promising downstaging data

- PanCO results highlighted the impact of downstaging patients to surgical resection
- Although downstaging was not planned, the 23.8% downstaging rate exceeds that in published phase 2/3 trials, comparing favourably to standard-of-care

## Large, unmet need

- Prognosis of pancreatic cancer remains poor; current treatment methods are relatively ineffective
- Opportunity for OncoSil™ to become the standard-of-care, supported by our breakthrough designation by FDA and in Europe

## Experienced team

- Experienced and accomplished commercial team in Europe and US
- Proven track records in the medical devices industry, able to leverage key existing relationships in the market (medical oncology, HPB surgery, nuclear medicine)

# Key activities over the past 6 months



## TEAM FINALISED

- ✓ Functions recruited include key account managers, training manager, chief medical officer, global head of medical affairs, health economics and reimbursement/market access



## OSPREY APPROVAL RECEIVED

- ✓ Formal approval received from HRA and REC in UK for 9 sites
- ✓ Progressing steps to establish OSPREY registry in other regions



## SUPPORTING APPLICATIONS

- ✓ Submitted additional data to the TGA (Australia) in January 2021, as requested
- ✓ Preparing updated data package for the FDA to support HDE application



## COVID-19 DELAYS

- ✓ COVID-19 has impacted approval timelines for many authorities/countries
- ✓ Limited-to-no access to hospitals has delayed launch, including onboarding, training and marketing activities at these sites

# Growth priorities

## Strategic priorities for OncoSil – EMEA and APAC

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### Supporting Key institutions

- Support 9 UK hospitals in London and Greater London to facilitate ramping up of patient treatments
- Initial focus on private payer market in EMEA and APAC as a primary source of early revenue
- Facilitating local ethics approvals for the OSPREY registry in other jurisdictions

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### Targeting reimbursement in key markets

- Comparative data is required to support reimbursement in the public sector
- While compelling, the PanCO study represents single-arm, non-comparative data
- OncoSil is developing a strategic clinical plan to meet these requirements – focusing on Germany and the UK

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### Capitalising on CE Marking approval

- CE Marking approval is recognised by many jurisdictions in EMEA and APAC
- OncoSil will continue to leverage its CE Marking and seek approvals in selected markets

# Growth priorities

## Strategic priorities for OncoSil – US

### 4 Immediate focus on HDE pathway for distal bile duct cancer

- Cost-effective, rapid pathway for entry into world's largest healthcare market
- HDE requirements are limited to a lower level of evidence, using pancreatic cancer data as a surrogate
- Once HDE is approved, OncoSil™ will be eligible for reimbursement through CMS
- Once CMS is approved, third-party reimbursement would follow

### 5 Develop strategy for PMA in locally advanced pancreatic cancer

- FDA affords the opportunity for OncoSil to work collaboratively and seek guidance on clinical trial design of a Phase II/III trial to support pre-market application (PMA)
- FDA breakthrough device designation coupled with CMS final rule ensures a reimbursement pathway for 4 years minimum<sup>1</sup>

# Building our Commercial and Clinical Expertise

## Additions critical to OncoSil as we commence global commercialisation

### Dr. Ralph Peters

#### Chief Medical Officer

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- 30+ years of experience in diagnostic and interventional radiology
- EMEA Medical Director of Sirtex Medical from 2005 - 2020
- Responsibilities at Sirtex included clinical development and support, market access and reimbursement, regulatory workstreams, site training and proctoring

### Mr. David Turner

#### Head of Medical Affairs

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- 40+ years experience in pharmaceutical, medical device and health technology industries
- 25+ years in commercial leadership roles including board and senior executive positions
- Most recently, David served as Global Head of Marketing for Sirtex Medical

### Mr. Olaf Michaelsen

#### Director, AREA<sup>1</sup>

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- 25+ years experience in implantable medical devices
- Previously held commercial leadership roles at Sirtex Medical, Medtronic and LifeCell
- 20+ years experience in market access, reimbursement, health economics and technology assessments in Europe

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The information contained in this presentation is current as at 18 February 2021.

**Nigel Lange**  
CEO & Managing Director  
E: [nigel.lange@oncosil.com](mailto:nigel.lange@oncosil.com)

OncoSil Medical Ltd  
[www.oncosil.com](http://www.oncosil.com)

T: +49 30 300 149 3043

