

#### **ASX Announcement**

07 August 2025

#### **Release of Investor Webinar Presentation**

OncoSil Medical Limited (ASX:OSL) ("OSL" or "the Company") is pleased to release the following investor webinar presentation to the market.

The presentation covers both the Company's achievements over the latter part of its recently completed 2025 financial year and commercialisation milestones expected to be delivered over the coming year, including:

- Drivers behind the record OncoSil<sup>™</sup> dose sales in Q4 FY25
- An update on OncoSil Medical's ongoing efforts to grow its geographic footprint, including some discussion on new regions being targeted (the US included)
- The steady stream of studies demonstrating superior outcomes from usage of the OncoSil™ device
- An explanation of the OncoSil™ device clinical study soon to be undertaken by the German Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA)
- Where the proceeds from the recent \$8.7m (before costs) capital raise will be directed.

#### Ends.

#### **Authorisation & Additional Information**

This announcement was authorised by the Chairman of OncoSil Medical Limited.

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#### About OncoSil Medical Limited (ASX:OSL)

OncoSil Medical (ASX:OSL) is a global medical device company focused on Interventional Oncology. OncoSil Medical's mission is to improve the outcomes for people living with cancer by utilizing the selected and targeted intratumoural placement of Phosphorous-32 (32P) Microparticles in addition to chemotherapy.

OncoSil Medical has developed OncoSil™ device for the treatment of unresectable locally advanced pancreatic cancer. Its targeted approach enables healthcare professionals to deliver a greater radiation dose directly into the tumour compared to external beam radiotherapy, while sparing surrounding critical organs.

Pancreatic cancer is the 12th most common cancer in men and the 11th most common cancer in women across the globe, with 500,000 new cases detected every year1. Since pancreatic cancer is generally diagnosed at a later stage, it has a poor prognosis for long-term survival.

OncoSil™ has received CE Marking approval, providing marketing authorisation in both the EU and the UK. OncoSil™ is designated as a breakthrough device in both Europe and the United States. It is currently approved for sale in 30+ countries including European Union, United Kingdom, Turkey and Israel, with commercial treatments using the device already undertaken in Spain, Italy, Austria, Greece, Turkey, and Israel.

To learn more, please visit: <a href="www.oncosil.com/">www.oncosil.com/</a>



# **OSL Update**

**August 2025** 

**Nigel Lange, CEO & Managing Director** 

**Targeted Approach • Positive Impact** 



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#### **Forward-Looking Statements**

This document contains certain forward-looking statements as at the date of this presentation relating to OncoSil's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA and other national authorities' requirements regarding any one or more product candidates, nor can there be any assurance that such product candidates will be approved by any authorities for sale in any market or that they will reach any particular level of sales, nor that that any specific objective of the Company will be achieved or that any particular performance of the Company or of its shares will be achieved.

In particular, the Company's expectations regarding the approval and commercialisation of the product candidates could be affected by, amongst other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; changes in legislation or regulatory requirements, our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our Company, products, product candidates, financial results and business prospects. Should one or more of these changes, risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. OncoSil is providing this information as of the date of this document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise. There is NO guarantee of future performance - actual results and future outcomes will in all likelihood differ from those outlined herein. You are urged to consider all of the above and advice from your own advisers carefully in evaluating the forward-looking statements and are cautioned not to place undue reliance on the forward-looking statements. The information in this presentation is not financial product advice, is not an offer to invest in the securities of OncoSil and does not take into account your investment position or objectives, financial situation or any particular requirements. For these and other reasons, you are strongly recommended to obtain your own up to date independent legal, financial and investment advice – those acting without such advice do so at their own risk.

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All dollar values are in Australian dollar (\$A) terms unless otherwise stated. Figures in this presentation are subject to rounding. The information contained in this presentation is current as of August 7, 2025

## Executive Summary



# Commercialising targeted radiotherapy for pancreatic cancer

- OncoSil Medical is commercialising the OncoSil<sup>™</sup> device, an implanted device (brachytherapy) delivering targeted radiation (<sup>32</sup>P) to pancreatic tumours –
- OncoSil<sup>™</sup> device is now **approved for sale in over 34 countries** via CE Mark
- Commercial ramp-up expected in FY26 and beyond following newly added markets and near-term market entry expectations
- Increasing market access via label expansion combining new delivery methods and new chemotherapy combinations<sup>1</sup>
- Accelerating market penetration with a shortened sales cycle and an increase in addressable hospital sites in the EU and UK
- Platform technology can be leveraged into other cancer indications (bile duct cancer, liver, glioblastoma)
- Experienced Board & Management team in the commercialisation of radiotherapies

#### • Granted Breakthrough Designation in the EU, UK and US with extensive patent coverage across all key geographies

- Large global pancreatic cancer patient population of ~510k p.a and targeting locally unresectable population of ~153k (~30%) with the market expected to increase by 37% by 2035<sup>2</sup>
- Negligible survival improvement in over 20 years with <12% survival rates at 5-years and 8.5 months Median Overall Survival</li>
- First ever Comparative analysis published May 2025 indicates significant benefit in combination with Chemotherapy:<sup>3</sup>
  - ✓ Overall Survival benefit of >7 months 20.0 months survival of OncoSil<sup>™</sup> + chemotherapy vs. 12.3 months in chemotherapy alone
  - ✓ More than doubled surgical resection rate 28.6% in Oncosil<sup>™</sup> + chemotherapy vs. 12.1% in chemotherapy alone
  - ✓ More than doubled patients downstaged 31.4% in Oncosil™ + chemotherapy vs. 13.6% in chemotherapy alone
  - ✓ Second Comparative Analysis presented May-25 confirms superiority for OncoSil™ + chemotherapy vs. chemotherapy + SBRT 5

# >US\$4.2bn global addressable market with no competition<sup>4</sup>

## Attractive unit economics

- Indicative ~US\$24k per device with Gross Margin expansion expected to increase from 50% to 65% in CY26 and target of >75% expected at scale
- Cost-out initiatives driving lower fixed cost base (20% reduction) with significant opportunity for operating leverage over the
  medium term
- Negligible additional capex required

## Executive Summary



## Significant recent achievements

- Received MDR approval and UKCA Certificate which includes the removal of all existing post-market restrictions in Europe and The UK (OSPREY registry) reducing hospital customers friction and accelerating adoption
- 100% Recruitment achieved in landmark PANCOSIL study (a groundbreaking delivery method for OncoSil™ device)
- 100% Recruitment achieved in TRIPP-FFX study (to expand OncoSil™ device label with additional chemotherapy combinations)
- New distribution agreements in Gulf Region, Egypt and Nordic countries
- ✓ Constructive discussions with US FDA regarding the approval pathway for OncoSil<sup>™</sup> device in Bile Duct Cancer (dCCA)
- Received German Federal Joint Committee (G-BA) approval and conditional reimbursement across 120 hospitals in Germany. Tender announced by G-BA now into second round short list.
- ✓ Filing for TGA submission completed in 2Q CY25

# Catalyst rich CY25/26

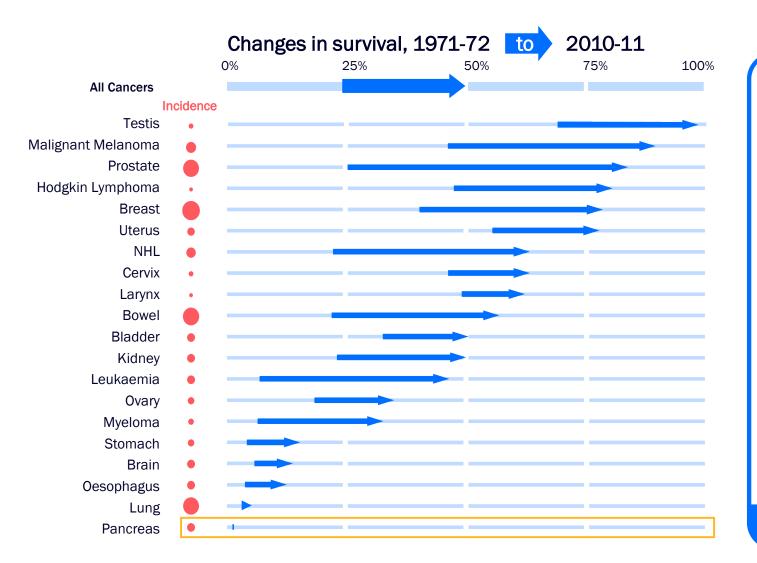
- At commercial ramp up in existing markets including Greece, Israel, Italy, Spain, Turkey,
- Accelerating commercial activities via expanded market access and geographical opportunities including:
  - Distribution agreements or direct representation in key markets including Argentina, Brazil, Chile, France, South Korea, South East Asia, Switzerland<sup>1</sup>
  - Label expansion to include delivery method for a new medical speciality, Interventional Radiology (PANCOSIL study) anticipated commercial availability late Q4 CY25
- First Commercial production in Sydney Manufacturing facility (anticipated late Q4 CY25)
- OncoSil device to be commercially available to interventional radiologists (anticipated late Q4 CY25)
- TGA approval (anticipated Q4 CY25)
- Commercial launch in Gulf Regions (anticipated H1 CY26)

#### **Equity raising**

- · Equity raising completed
  - Two-tranche institutional placement of \$6,7M
  - Share purchase plan \$2,0M (oversubscribed by \$2.4M)
  - 1 for 400 share consolidation completed prior to equity raise

## Pancreatic Cancer Prognosis has Remained Unchanged for 40 Years Oncosil





#### **Survival rates are very poor:**

- 8.5 months overall median survival
- <12% reach 5-year survival<sup>2</sup>
- Lower survival rate than any other cancer<sup>3</sup>
- The number of cases and deaths both estimated to increase by 40% before 2035<sup>3</sup>

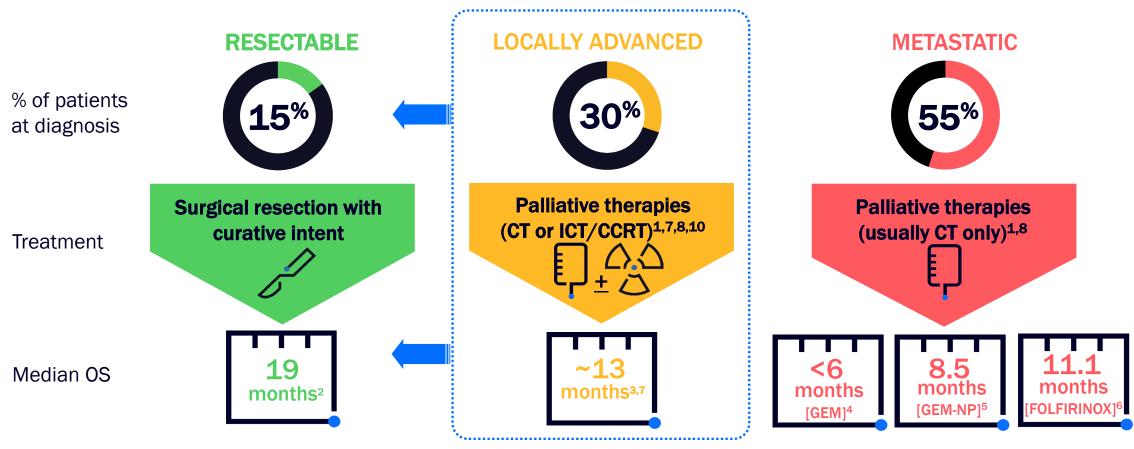


New therapeutic options urgently needed

## Pancreatic Cancer Stage at Diagnosis



Surgical resection remains the only potentially curative treatment for pancreatic cancer<sup>1</sup>



30% of LAPC patients show metastatic progression within 3-6 months<sup>9,10</sup>

### OncoSil<sup>™</sup> Device



#### Driving increased resection rates, downstaging, survival benefits and quality of life

OncoSil™ is intended for the treatment of locally advanced unresectable pancreatic

cancer, in combination with gemcitabine-based chemotherapy

(combination with FOLFIRINOX

currently in trials)

OncoSil<sup>™</sup> is currently implanted directly into a pancreatic tumour via injection under endoscopic ultrasound guidance



98% of all radiation is delivered within 81 days of injection causing damage to cancer cell DNA and killing malignant cancer cells with no damage to surrounding tissue

OncoSil<sup>™</sup> is a **single-use** brachytherapy device comprised of microparticles and a diluent

cells with no d
surround
ervised procedure

Requires only one supervised procedure given simplicity and familiarity with standard, everyday, biopsy procedures

Percutaneous delivery is transformational and anticipated to significantly accelerate market penetration:

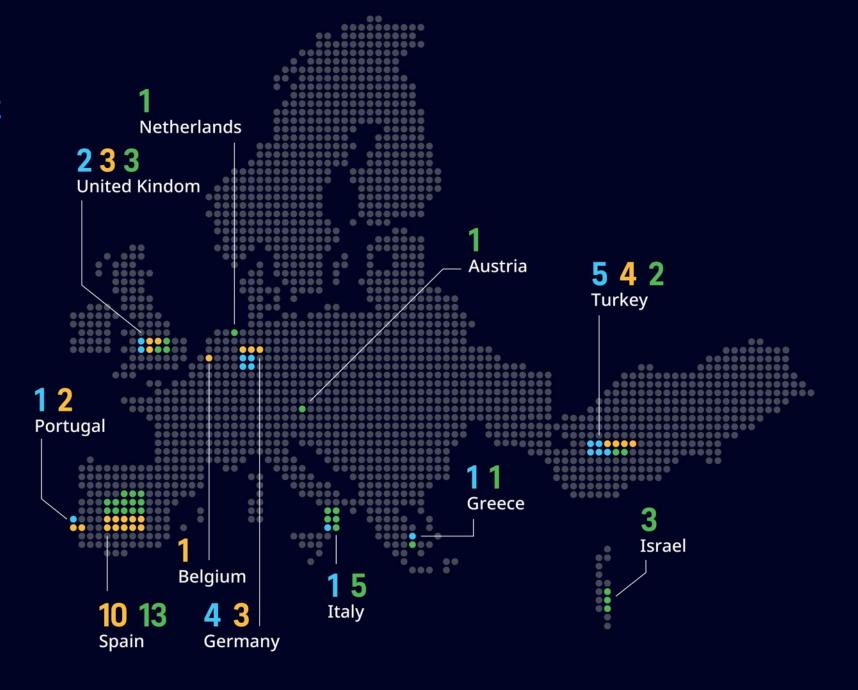
- Expanding the number of treating clinicians to include Interventional Radiologists
- Broader patient access and points of care
- Outpatient day procedure complete within 20 minutes
- Conscious sedation (patient awake)

PANCOSIL study anticipated to complete in Q2 CY25 – topline readout in Q3 CY25

Targeting Q4 CY25 to make OncoSil™ commercially available to Interventional Radiologists

# Training New Sites to start OncoSil<sup>TM</sup> treatments

- Training Commenced
- Training Completed and ready to start
- Sites using OncoSil



## Commercial Market Expansion



#### **Existing Priority Markets**

Target Market	Pancreatic Cancer Incidence p.a. <sup>1</sup>	Locally Advanced Pancreatic Cancer <sup>2</sup>	Market Opportunity (\$USm	
UK	11,852	3,556	~91	
Spain	9,282	2,785	~68	
Italy	16,111	4,833	~118	
Germany	22,587	6,776	~174	
Greece	2,343	703	~17	
Austria	2,250	675	~17	
Turkey	9,012	2,704	~54	
Portugal	2,217	665	~16	
Israel	1,249	375	~9	
Saudi Arabia	666	200	~6	
Hong Kong	1,116	335	~8	
Egypt	3,649	1,095	~\$22	
Nordic Region	6,871	2,061	~\$50	
Total (Existing)	89,205	26,762	~651	
Near-Term Target Markets				
South Korea	10,046	3,014	~74	
France	16,538	4,961	~122	
Brazil	15,383	4,615	~113	
Argentina	5,979	1,794	~44	
Netherlands	3,689	1,107	~27	
South East Asia	13,723	4,117	~101	
Others	6,588	1,976	~48	
Total (New)	71,946	21,584	~529	



Geographies include the Nordic Region and Egypt newly added

Expanding to >US\$1.1bn addressable market over next 18 -24 months

Market Penetration expected to now accelerate over the near-term driven by:

 Percutaneous Delivery following a target Q4 CY2025 label expansion



## Accelerating Commercialisation



#### **Compelling cost-benefit proposition with no direct competition**

#### **Attractive Unit Economics**



- Average list price of ~€22k/~US\$24k
- Gross Margin of 50% expected to increase to 65% driven by manufacturing productivity and **targeting >75%** device margins at scale

#### **No direct Competition**



- Granted Breakthrough Designation in the US, EU, UK
- The only commercially available, or in development, targeted Radiotherapy for LAPC
- Patented technology that is difficult to reverse engineer

## Capital light operating model



- Concentrated industry structure with high volumes undertaken at 'centres of excellence'
- High Return on Capital with relatively small sales force required in direct markets to drive adoption
- High operating leverage anticipated through economies of scale in the long-term

# Commercial scale manufacturing capability



- End-to-end manufacturing capabilities and logistics already in place and able to meet commercial quantities
- Second manufacturing facility (Sydney, Australia) expected to be accretive to Gross Margin and producing first commercial doses in Q4 CY25

# Multiple high value initiatives to broaden market access & accelerate commercialisation



- Label expansion to include additional method of delivery (PANCOSIL study Expected completion Q2 CY25
- Label expansion to include additional chemotherapy combination (TRIPP-FFX study expected completion Q2 CY25
- **Expansion into new markets** (Argentina, Brazil, Chile, France, Hong Kong, Sout East Asia, South Korea, Switzerland)

Reference: EURUSD 1.1133 (19 May 2025).

## **Enhancing Market Access**

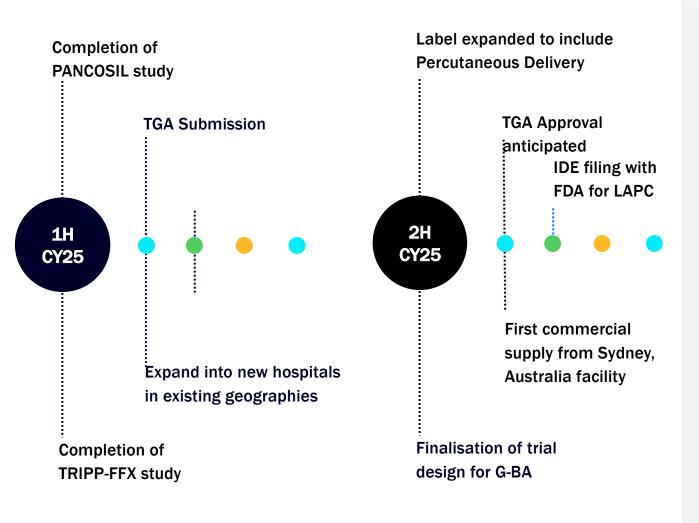


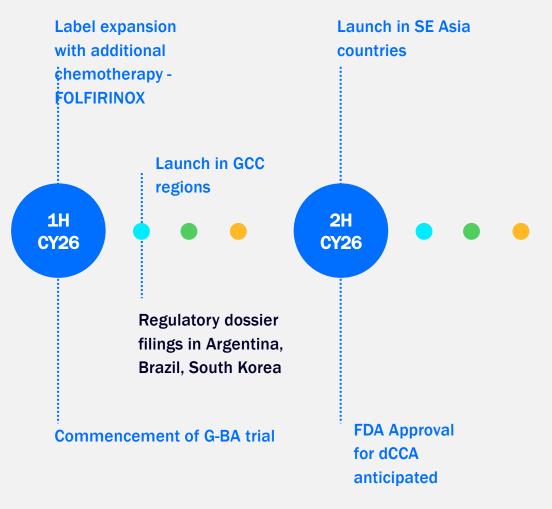
Program	Description	Key Milestones	Commercial Impact
Bile Duct Cancer	Bile Duct Cancer (Distal Chalingiocarcinoma - dCCA) For approval by US FDA under Human Device Exemption (HDE)	<ul> <li>Discussions remain ongoing and constructive with US FDA</li> <li>OncoSil is preparing additional data to support HDE application</li> </ul>	Small addressable market however a supportive pathway to US market entry for LAPC
G-BA Trial	120 German Hospitals to negotiate reimbursement of the OncoSil™ device under the innovation funding program (NUB). Currently awaiting confirmation from German Public Health Agencies Federal Joint Committee (G-BA)	<ul> <li>G-BA approval received Oct-24</li> <li>Procedural finalisation from Ministry of Health Q1 2025</li> <li>CRO selection into 2<sup>nd</sup> round, protocol synopsis and trial design</li> <li>Expected completion date Q4 CY27</li> </ul>	Public insurance reimbursement for OncoSil™ device in Germany for trial participants Opportunity to participating hospitals to receive reimbursement for patients not participating in trial
PANCOSIL	Feasibility and safety of CT-guided percutaneous radionuclide therapy with OncoSil <sup>™</sup> device + Chemotherapy in non-progressive locally advanced pancreatic cancer	<ul> <li>100% recruitment achieved (20/20)</li> <li>Fully enrolled Q3 CY25</li> <li>Regulatory submission target of Q3/4 CY25 <ul> <li>Added to Label - targeted commercial</li> <li>launch in EU and UK markets in Q4 CY25</li> </ul> </li> </ul>	Accelerates market penetration with lower barriers to adoption via a new method of delivery for a new medical speciality (Interventional Radiology)
TRIPP-FFX	Efficacy and Safety of Oncosil combined with standard Folflirinox chemotherapy vs. FOLFIRINOX chemotherapy alone	<ul> <li>100% recruitment achieved (88/80)</li> <li>Fully enrolled Q3 CY25</li> <li>Target Regulatory submission Q3/4 CY25</li> <li>Added to Label in all approved jurisdictions H2 CY26</li> </ul>	Accelerates market penetration with label expansion to include coverage of OncoSil™ device with all typical LPAC chemotherapy regimens (EU region)

## Upcoming Milestones

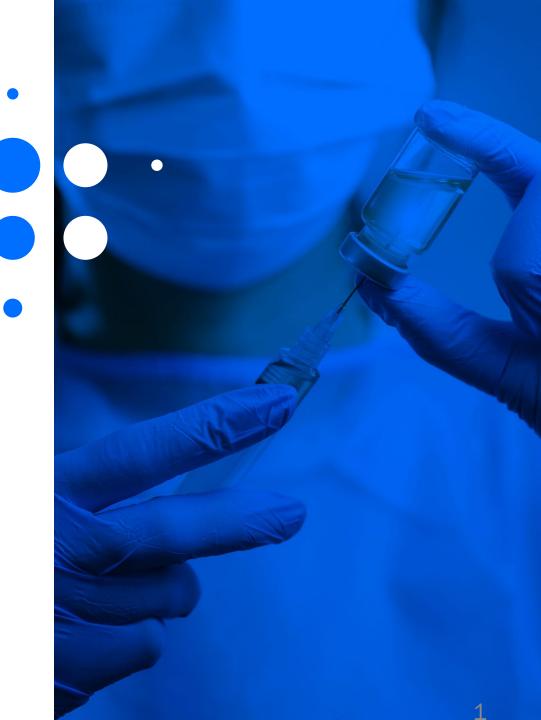


### Significant commercial catalysts over the next 18 months





# **Leadership Team**



## Experienced Board and Management



#### **Depth in Nuclear Medicine Commercialisation**



Douglas Cubbin Non-executive Chairman

30+ years' biopharmaceutical experience in senior roles across varied industries.

Had a key role at Telix Pharmaceuticals (ASX:TLX) for +5 yeas, including IPO.



Dr Thomas Duthy Non-executive Director

20+ years of experience across financial markets, corporate development and board-level roles, involved in numerous successful M&A transactions.



Lel Smits Non-executive Director

Award-winning entrepreneur, director and investor relations advisor, serving as a Director on Australian Shareholders' Association since 2021.



Nigel Lange Managing Director & CEO

30+ years' experience in medical device industry.

Served as Group COO and Interim Group CEO of Sirtex Medical (ASX:SRX).



Shelley Steyn Chief Financial Officer

Extensive experience in senior accounting, commercial and financial analysis, and audit roles across listed and private companies.



Dr Jon Bell MD Chief Medical Officer

12 years' experience as consultant interventional radiologist and an internationally recognised expert in interventional oncology.



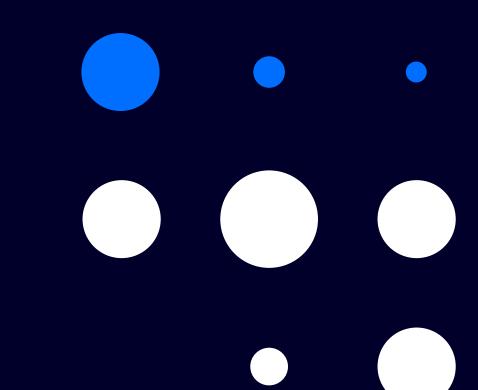
### **Nigel Lange**

**CEO & Managing Director** 

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#### **Learn more about OncoSil Medical:**

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- ASX announcements
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