

**ASX Announcement**

**15 November 2024**

## **Investor Webinar Presentation**

**The webinar will update investors on recent and pending developments  
in the commercialisation strategy for OncoSil Medical's unique MedTech**

**OncoSil Medical Limited (ASX:OSL) Chief Executive Officer & Managing Director Nigel Lange will present an investor webinar today, Friday 15 November 2024.**

The webinar will be hosted by The Capital Network's Julia Maguire.

In his presentation, Nigel Lange will highlight:

- Recent milestones achieved in OncoSil Medical's ongoing efforts to become a leading treatment option for pancreatic cancer – both in Australia and overseas
- The commercial significance of these milestones, the recently announced G-BA approval for the OncoSil™ device included as well as the MDR approval
- Key objectives of OncoSil Medical's near and medium-term growth strategy.

A copy of the presentation is attached.

### **OncoSil Medical Investor Webinar Registration Details:**

**DATE:** Friday 15 November 2024

**TIME:** 11.00-11.45 AM AEDT

**FORMAT:** Zoom

**Please register in advance using the following link:**

[https://us02web.zoom.us/webinar/register/WN\\_65xZe6h9TJgPqmUwMhHlkg](https://us02web.zoom.us/webinar/register/WN_65xZe6h9TJgPqmUwMhHlkg)

After registering, you will receive a confirmation email containing information about joining the webinar.

**Ends.**

## Authorisation & Additional Information

This announcement was authorised by the CEO & Managing Director of OncoSil Medical Limited.

### For further information, please contact:

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### About OncoSil Medical

OncoSil Medical Limited (ASX:OSL) has developed a cancer treatment device, the OncoSil™ brachytherapy device, which is a critical component of a revolutionary brachytherapy treatment for locally advanced unresectable pancreatic cancer. This type of cancer is the 12<sup>th</sup> most common cancer in men and the 11<sup>th</sup> most common cancer in women across the globe, with some 500,000 new cases of pancreatic cancer detected every year. With pancreatic cancer typically diagnosed at a later stage, it has a poor prognosis for long-term survival<sup>1</sup>.

The OncoSil™ device delivers a targeted intratumoural placement of Phosphorous-32 (<sup>32</sup>P) in the treatment of locally advanced unresectable pancreatic cancer. This occurs via injection directly into a patient's pancreatic tumours under endoscopic ultrasound guidance and takes place in combination with gemcitabine-based chemotherapy.

The OncoSil™ device that has already received breakthrough device designation in the European Union, United Kingdom and United States for the treatment of locally advanced unresectable pancreatic cancer in combination with chemotherapy. CE Marking has additionally been granted for the OncoSil™ device, which can be marketed in the European Union, United Kingdom.

While clinical trials involving the OncoSil™ device continue to occur, the Company is simultaneously moving to commercialise this unique medical technology. It is currently approved for sale in 30+ countries including European Union, United Kingdom, Türkiye and Israel, with initial commercial pancreatic cancer treatments using the device already undertaken in Spain, Italy and Israel.

To learn more, please visit: [www.oncosil.com/](http://www.oncosil.com/)

**References:** 1. <https://www.wcrf.org/cancer-trends/pancreatic-cancer-statistics/>



# Webinar Presentation

November 15, 2024

Nigel Lange, CEO & Managing Director

Targeted Approach • Positive Impact

ASX Code: OSL



# • Disclaimer

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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 and international 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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The information contained in this presentation is current as at 15 November 2024.

# • Executive Summary

## Commercialising targeted radiotherapy for pancreatic cancer

- OncoSil Medical is commercialising the OncoSil™ device, an implanted device (brachytherapy) delivering targeted radiation (<sup>32</sup>P) to pancreatic tumours – In Oct-24, OncoSil Medical treated its **200<sup>th</sup> patient**
- OncoSil™ device is now **approved for sale in over 34 countries** via CE Mark
- **Commercial ramp-up expected in FY25** 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

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

- 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
- **First ever Comparative analysis released in Sep-24 indicates significant benefit in combination with Chemotherapy:<sup>3</sup>**
  - ✓ ***Overall Survival benefit of 7 months*** – 20.0 months survival of OncoSil™ + chemotherapy vs. 13.0 months in chemotherapy alone
  - ✓ ***More than doubled surgical resection rate*** – 28.6% in OncoSil™ + chemotherapy vs. 12.1% in chemotherapy alone
  - ✓ ***More than doubled patients downstaged*** – 31.4% in OncoSil™ + chemotherapy vs. 13.6% in chemotherapy alone

# • Executive Summary

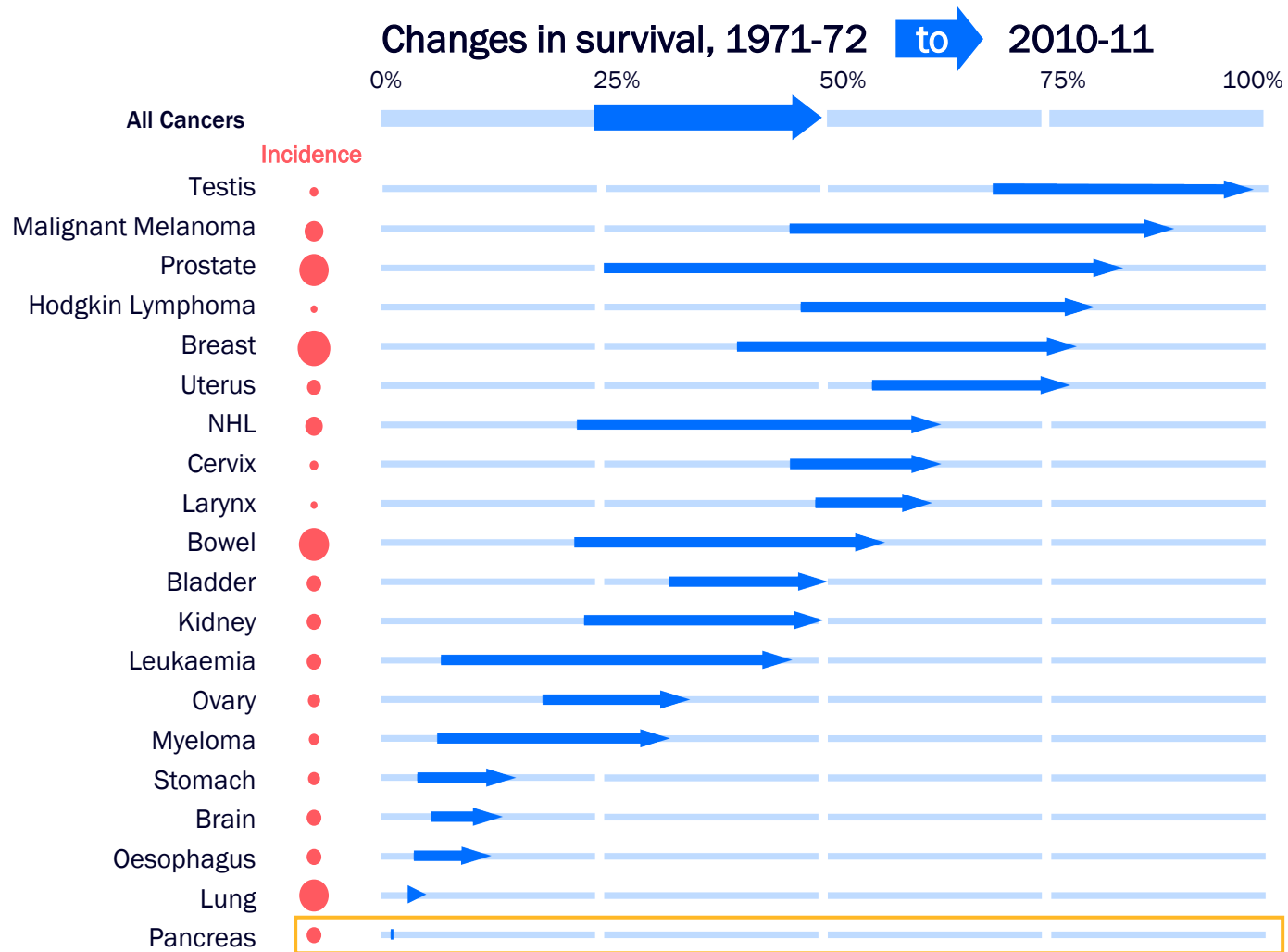
## Significant achievements over CY24

- Received UKCA Certificate which includes the removal of all existing post-market restrictions in the UK (OSPREY registry)
- 70% Recruitment achieved in landmark PANCOSIL study (a groundbreaking delivery method for OncoSil™ device)
- 59% Recruitment achieved in TRIPP-FFX study (to expand OncoSil™ device label with additional chemotherapy combinations)
- Second manufacturing facility in Sydney, Australia activated and ready to undergo validation.
- New distribution agreements in UAE, Qatar, Oman, Bahrain, Saudi Arabia, Nordics, Egypt and Turkey
- Constructive discussions with US FDA regarding the approval pathway for OncoSil™ device in Bile Duct Cancer (dCCA)
- Received German Federal Joint Committee (G-BA) approval and conditional reimbursement across 84 hospitals in Germany

## Catalyst rich CY25/26

- At commercial ramp up in existing markets including Austria, Greece, Israel, Italy, Spain, Turkey, UK
- Medical Device Regulation (MDR) approval anticipated in Q4 2024 expected to accelerate market penetration in EU regions
- Accelerating commercial activities via expanded market access and geographical opportunities including:
  - *Distribution agreements or direct representation in key markets including Argentina, Brazil, Chile, Egypt, France, Nordic countries, South Korea, Switzerland<sup>1</sup>*
  - *Label expansion to include delivery method for a new medical speciality, Interventional Radiology (PANCOSIL study) – submission expected Q2 CY25*
- Therapeutic Goods Administration (TGA) filing in (Q1 CY25)
- First Commercial production in Sydney Manufacturing facility (Q2 CY25)
- Regulatory filings in Argentina and Brazil (2Q CY25)

# • Pancreatic Cancer Prognosis has Remained Unchanged for 40 Years<sup>1</sup>



## 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>

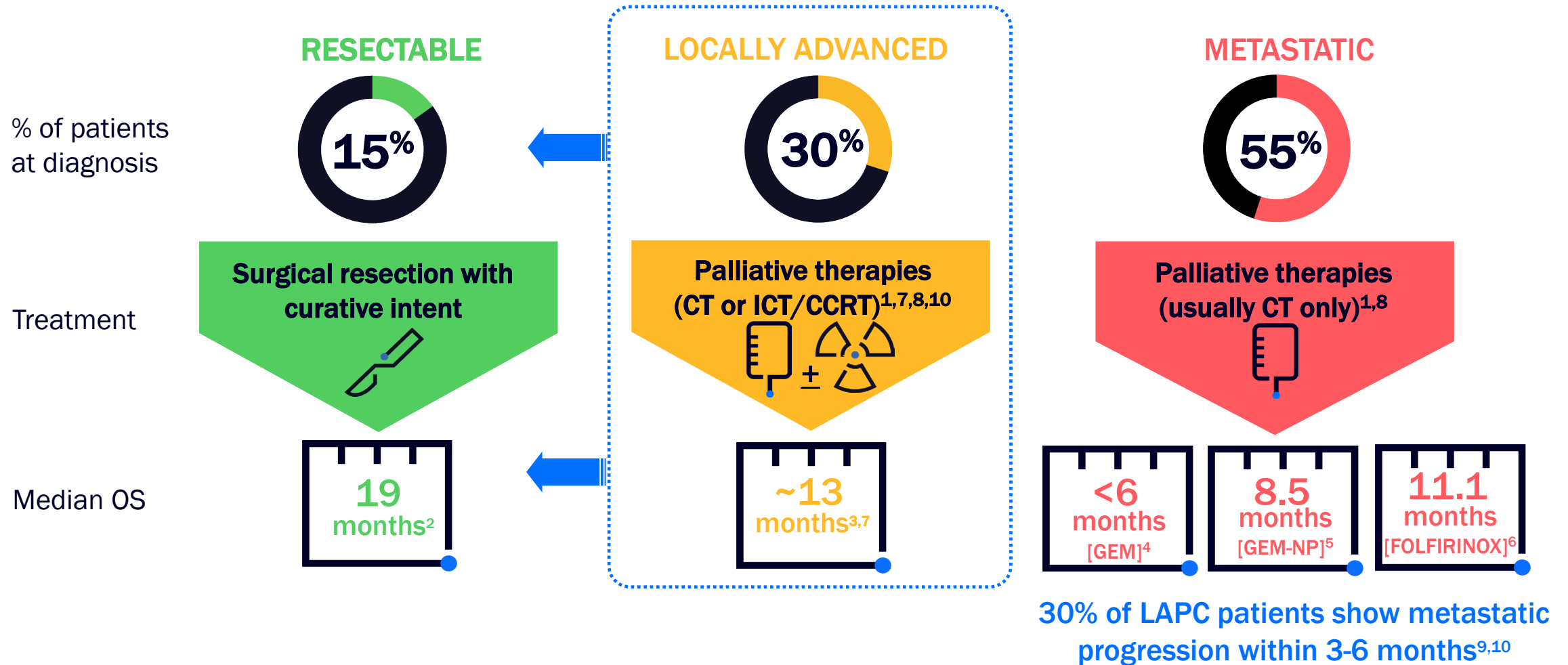


New therapeutic options urgently needed



# • Pancreatic Cancer Stage at Diagnosis

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



**Abbreviations:** CT: Chemotherapy; ICT: Induction chemotherapy; CCRT: Concurrent chemoradiation therapy.

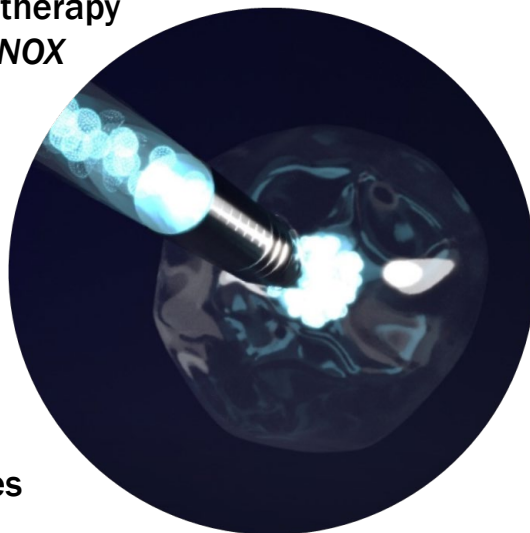
**References:** <sup>1</sup>. Ducreux M et al. Ann Oncol 2015; 26 (Suppl 5): v56–68. <sup>2</sup>. van Dam JL et al. Eur J Cancer. 2022; 160: 140–149. <sup>3</sup>. Chang JS et al. Cancer Res Treat 2018; 50: 562–574 (suppl data). <sup>4</sup>. Burris HA 3rd et al. J Clin Oncol 1997; 15: 2403–2413. <sup>5</sup>. Von Hoff DD et al. N Engl J Med 2013; 369: 1691–1703. <sup>6</sup>. Conroy T et al. N Engl J Med 2011; 364: 1817–1825. <sup>7</sup>. Balaban EP et al. J Clin Oncol 2016; 34: 2654–2668. <sup>8</sup>. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Pancreatic adenocarcinoma. Version 1.2020. <sup>9</sup>. Huguier et al. J Clin Oncol 2010. <sup>10</sup>. Mukherjee et al, Lancet Oncol 2013.



## 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™ is a **single-use** brachytherapy device comprised of microparticles imbedded with  $^{32}\text{P}$  and a diluent



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

OncoSil™ 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**



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

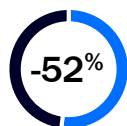
- ✓ Expanding the number of treating clinicians to include Interventional Radiologists
- ✓ Broader patient access and points of care
- ✓ Outpatient day procedure – complete within 20 minutes
- ✓ Conscious sedation (patient awake)

PANCOSIL study anticipated to complete in Q1 CY25 – **topline readout end Q2 CY25**

**Targeting Q3 CY25 to make OncoSil™ commercially available to Interventional Radiologists (regulatory approval)**

# • OncoSil™ plus Standard-of-Care Chemotherapy

## Landmark analysis supports evidence of transforming prognosis and extending survival



Adding OncoSil™ to chemotherapy led to a high proportion of patients having **substantial reductions in their tumour volume** (median 51.9%; range +11% to -90%), **with 60% having a >50% reduction<sup>2</sup>**



**Local disease control at 16 weeks in 90.5% of treated patients** – meeting the primary efficacy measure and statistically significant compared to the pre-set hypothesis



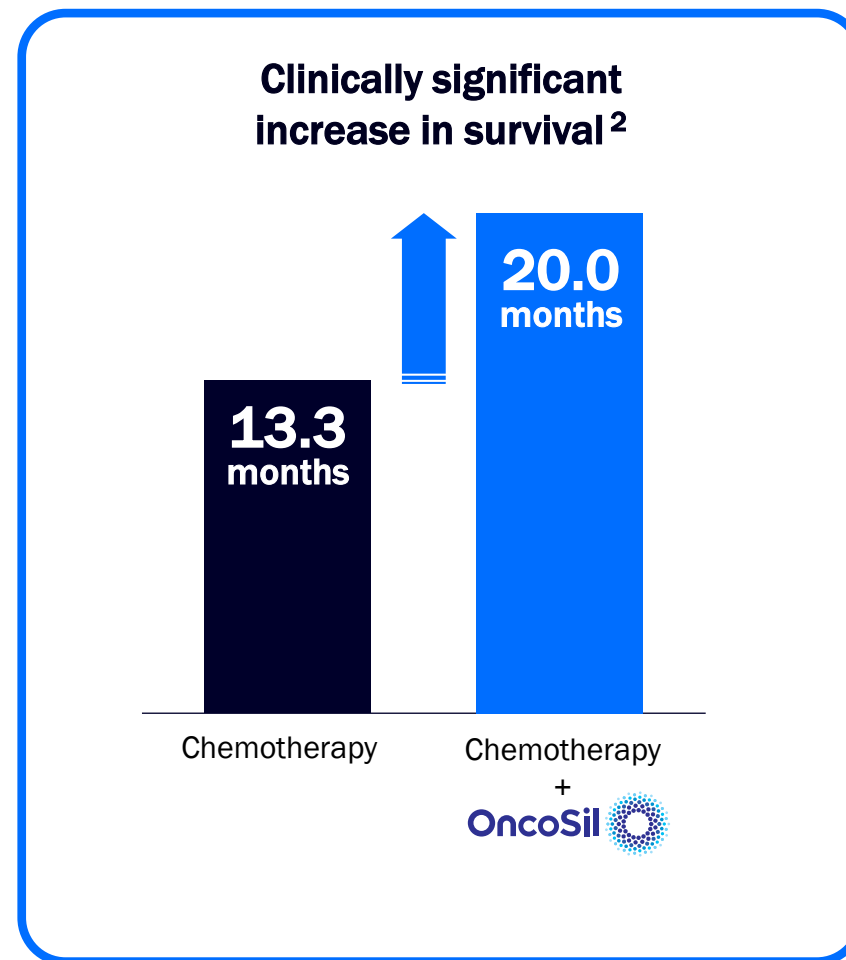
**Significantly increased survival** in those receiving OncoSil™ compared to chemotherapy alone in a propensity score analysis: median overall survival 20.0 vs. 13.3 months (p=0.001), with 3.7 months (+32.3%) longer restricted mean survival time (RMST) at 24 months from starting treatment<sup>2</sup>



OncoSil™ also **significantly increased both local and distant Progression-Free Survival (PFS)** compared to chemotherapy alone in a propensity score analysis: median local PFS was 14.7 vs. 10.0 months (p<0.01), with 3.7 months (+41.3%) longer RMST at 24 months from starting treatment<sup>2</sup>



**Established safety profile with no evidence of additional risk from adding OncoSil™ to standard-of-care chemotherapy**



**Abbreviations:** PFS: Progression-free survival; RMST: Restricted mean survival time.

**References:** 1. Ross PJ et al. Results of a single-arm pilot study of 32P microparticles in unresectable locally advanced pancreatic adenocarcinoma with gemcitabine/ nab-paclitaxel or FOLFIRINOX chemotherapy. ESMO Open February 2022; 7 (1): 100356. 2.

Lim A et al. Combined phosphorus-32 implantation and chemotherapy: A comparison with standard therapy using a propensity-score weighted landmark analysis and an assessment of its impact on vascularity in locally advanced pancreatic cancer.

Presented at the Gastroenterological Society of Australia's Australian Gastroenterology Week (AGW 24) Meeting; 14–16 September 2024. Journal of Gastroenterology and Hepatology 2024; 39 (Suppl. 1): 39 Abs, 337.

# OncoSil™ plus Standard-of-Care Chemotherapy

At least doubling the number achieving surgical resection or downstaging compared to chemotherapy alone<sup>1,2</sup>



Around 1 in 4 patients (23.8% in PanCO; 28.6% in the Propensity Score analysis) with unresectable LAPC receiving OncoSil™ plus chemotherapy **underwent surgery with curative intent, compared with resection rates of 12.1% of patients receiving chemotherapy alone in the Propensity Score analysis** <sup>1,2</sup>

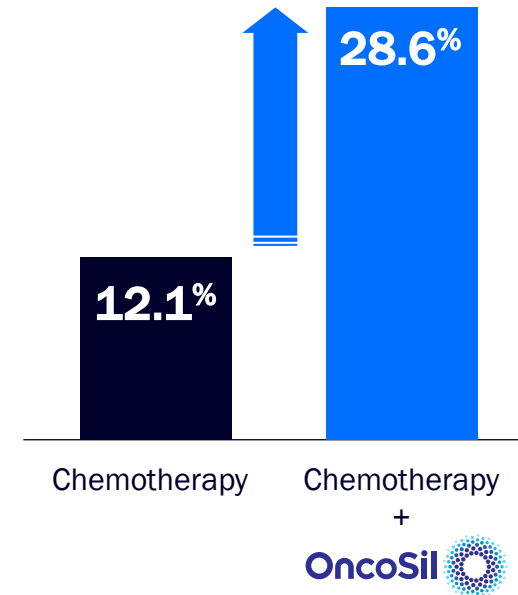


Nearly 1 in 3 patients (33.3% in PanCO; 31.4% in the Propensity Score analysis) **were downstaged** (tumour size reduced sufficiently to allow surgical resection, independent of whether the patient is fit for surgery), **compared 13.6% of patients receiving chemotherapy alone in the Propensity Score analysis** <sup>1,2</sup>

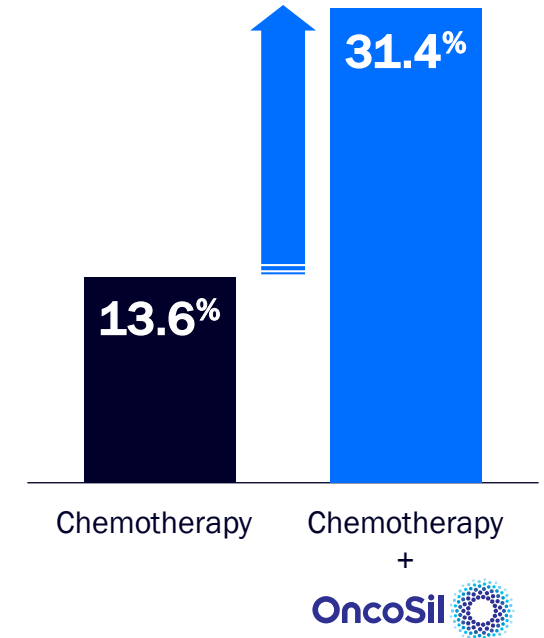


6 of the 10 resected patients in the PanCO study **remained alive, 5 having no evidence of disease, at 32.0 months median follow-up from enrolment in the study** <sup>1</sup>

More than doubled the number surgically resected<sup>2</sup>



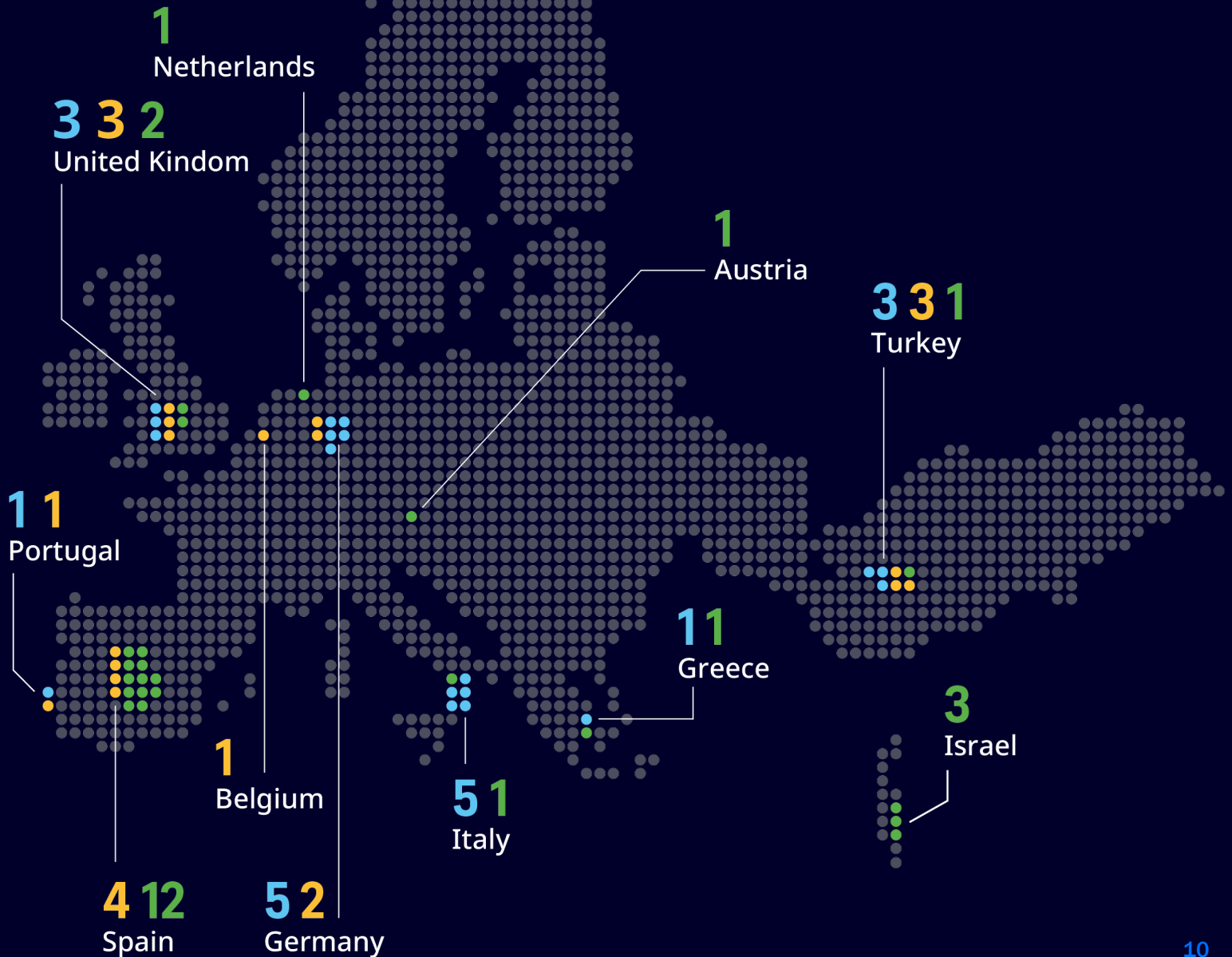
More than doubled the number downstaged<sup>2</sup>



# • Growing Global Adoption

Sites undertaking  
OncoSil™ Device  
treatments continue  
to grow

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



# • Significant Commercial Opportunity

## Existing Priority Markets

Target Market	Pancreatic Cancer Incidence p.a. <sup>1</sup>	Locally Advanced Pancreatic Cancer <sup>2</sup>	Market Opportunity (\$USm)
UK	12,710	3,813	~98
Spain	8,946	2,684	~66
Italy	15,181	4,554	~112
Germany	22,727	6,818	~175
Greece	2,422	727	~18
Austria	2,181	654	~17
Turkey	9,888	2,966	~66
Portugal	1,920	576	~14
Israel	1,336	401	~10
Saudi Arabia	745	224	~6
Hong Kong	1,116	335	~8
<b>Total (Existing)</b>	<b>79,172</b>	<b>23,752</b>	<b>~588</b>

## Near-Term Target Markets

South Korea	8,891	2,667	~65
France	15,596	1,114	~27
Switzerland	1,958	4,679	~115
Brazil	14,670	701	~17
Argentina	5,554	587	~14
Chile	1,899	4,401	~108
Netherlands	3,714	1,666	~41
Belgium	2,338	570	~14
<b>Total (New)</b>	<b>54,620</b>	<b>16,386</b>	<b>~401</b>



OncoSil™ device remains **at the early-stage of commercialization** in existing geographies with ~US\$588m market size

Expanding to ~US\$990m addressable market over next **18 –24 months**

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

- Full MDR approval to replace existing post-market restrictions in UK/EU; and
- Percutaneous Delivery following a target Q3 CY2025 label expansion

# • Eliminating Barriers to Hospital Adoption

MDR approval anticipated to increase market penetration across EU and UK markets

## Current Status

OSPREY Post Market Registry in EU and UK adds multiple layers of administration and complexity for approving and onboarding clinical sites

Increased time to onboard hospitals with up to six months to clear hospital ethics committee

Company incurs costs for ethics committee applications and Clinical Research Organisations (CROs) related to patient recruitment



## Incoming changes

- OncoSil has now received the UK Conformity Assessment Certificate removing all post-market restrictions in the UK market, including OSPREY
- OncoSil is expecting to receive full Medical Device Regulation (MDR) approval in the near-term given confidence by the regulatory authorities in the clinical safety data for the OncoSil™ device
- Implementation of the MDR is to replace the requirement for OSPREY Registry in EU in addition to the UK and results in:
  - ✓ Removal of administrative burden and requirement for ethics committee approval with six months saved to onboard new hospital accounts
  - ✓ Only isotope (<sup>32</sup>P) license required at new hospital accounts (all current hospital sites have required license)
  - ✓ Company to save €2 million over three years in ethics approval and patient recruitment related costs

# • Accelerating Commercialisation

## Enhancing market access in existing and new geographies

Program	Description	Key Milestones	Commercial Impact
PANCOSIL	Feasibility and safety of CT-guided percutaneous radionuclide therapy with OncoSil™ device + Chemotherapy in non-progressive locally advanced pancreatic cancer	<ul style="list-style-type: none"><li>70% recruitment achieved (14/20)</li><li>Target Study completion Q1 2025</li><li>Regulatory submission target of Q2 2025<ul style="list-style-type: none"><li>Added to Label and targeted commercial launch in EU and UK markets in 2H25</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 Folfirinox chemotherapy vs. FOLFIRINOX chemotherapy alone	<ul style="list-style-type: none"><li>59% recruitment achieved (47/80)</li><li>Target completion Q3 CY25</li><li>Target Regulatory submission Q3/4 CY25</li><li>Added to Label in all approved jurisdictions H1 CY26</li></ul>	Accelerates market penetration with label expansion to include coverage of OncoSil™ device with all typical LPAC chemotherapy regimens (EU region)
Bile Duct Cancer	Bile Duct Cancer (Distal Cholangiocarcinoma - dCCA) For approval by US FDA under Human Device Exemption (HDE)	<ul style="list-style-type: none"><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



# • Accelerating Commercialisation

## Commercial Significance of G-BA CED\* Trial

Program	Description	Key Milestones	Commercial Impact
G-BA Trial	German Hospitals free to negotiate reimbursement of the OncoSil™ device under the innovation funding program (NUB) in clinically treated patients. G-BA currently awaiting formal signature from German MoH.	<ul style="list-style-type: none"><li>• G-BA approval <b>received Oct-24</b></li><li>• Procedural finalisation from Ministry of Health Q1 2025</li><li>• Expected completion date of trial Q4 CY27</li></ul>	Public insurance reimbursement for OncoSil™ device in Germany for trial participants. <b>Opportunity for participating hospitals to receive reimbursement for patients not participating in trial.</b>



Top 10 German pancreatic cancer centers performed ~2,000 complex surgeries in 2023. These represent our primary targets for commercial adoption.

# • PANCOSIL: Expanding Market Access – Novel Delivery Method

Greater market access for OncoSil™ with the adoption of Interventional Radiology/Oncology medical specialty

**Trial in  
progress**



To assess the safety and feasibility of percutaneous CT-or ultrasound-guided RNT using the OncoSil™ device in patients with non-progressive LAPC after induction chemotherapy treatment

**70%  
recruited**



Amsterdam UMC & Antonius Hospital Nieuwegein – (14/20 subjects)

**Primary  
Endpoint**



Safety and feasibility of percutaneous RNT using the OncoSil™ device defined by the percentage of device or procedure-related CTCAE grade 3 or higher adverse events, until 90 days post-procedure

**Objective**



Expanded Commercial use of OncoSil™ device by Interventional Radiologists/Oncologists

## Commercial ramp up with upside expected from new market access initiatives

Unit volumes are expected to ramp up materially following onboarding activities in existing initial markets in CY24

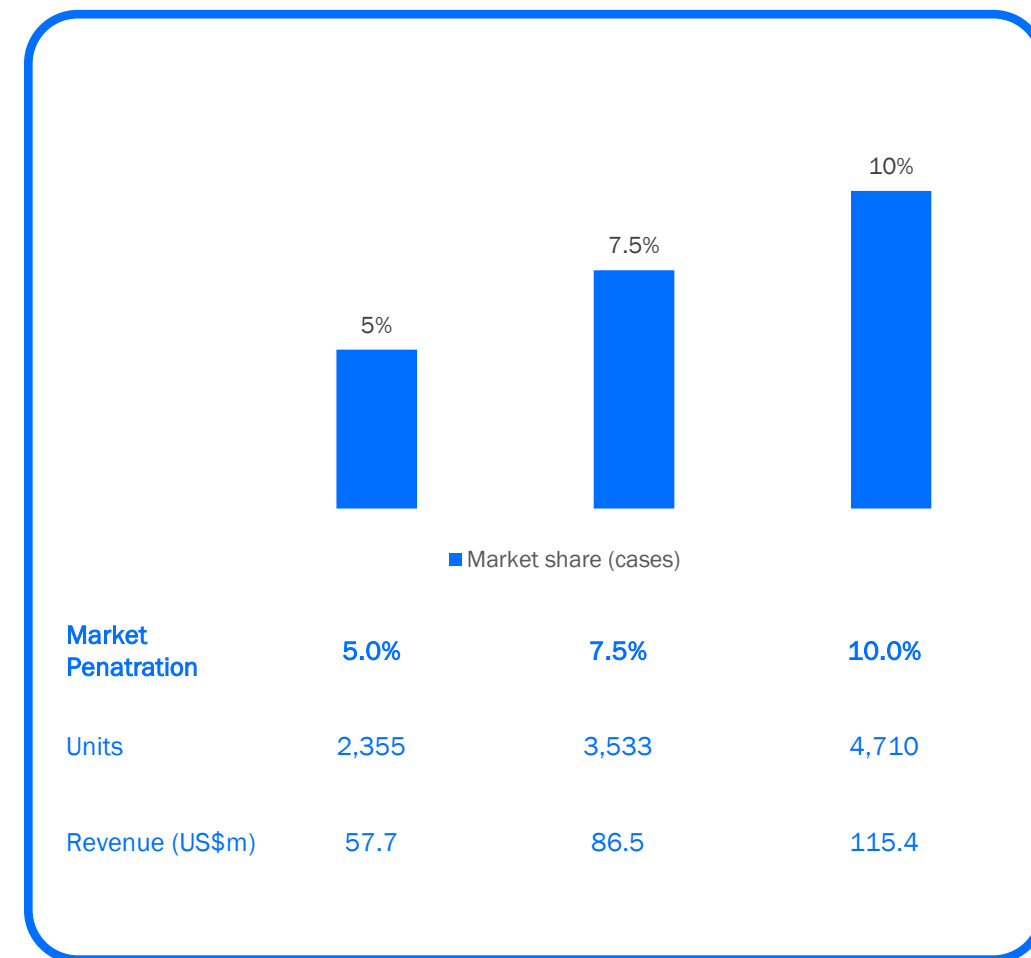
Volumes in existing markets are expected to underpin growth from market entry expectations over the near-term

OncoSil™ has an aspirational target of 5–10% market penetration by CY29 in existing and near-term target markets implying up to 4,710 units p.a.

Label expansion activities enhancing market access including:

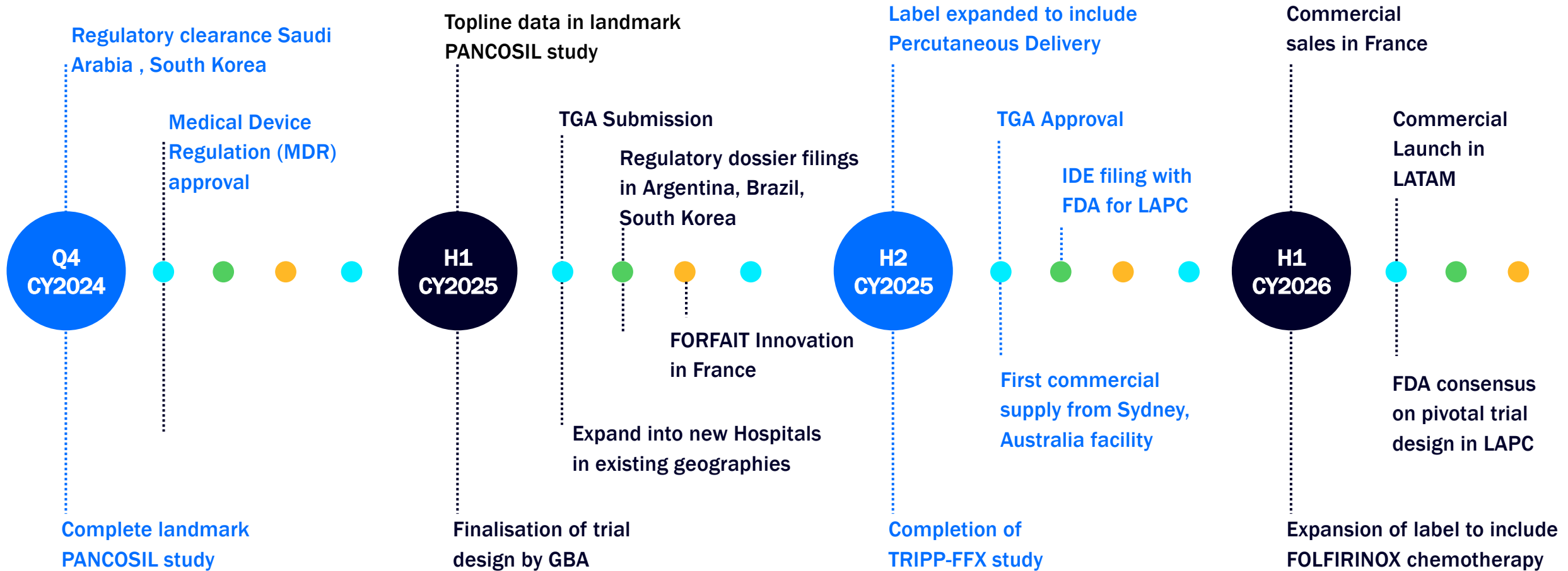
- Percutaneous delivery method for new clinician group (Interventional Radiologists); and
- Combination with FOLFIRINOX chemotherapy

 Is expected to significantly accelerate current aspirational volume targets



# Upcoming Milestones

## Significant catalysts over the next 24 months





## Nigel Lange

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### Learn more about OncoSil Medical:

- [Website](#)
- [ASX announcements](#)
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Targeted Approach • Positive Impact

