



OncoSil Limited (ASX:OSL)

Developing pancreatic cancer treatment

Investor presentation – July 2024

Nigel Lange – CEO & Managing Director



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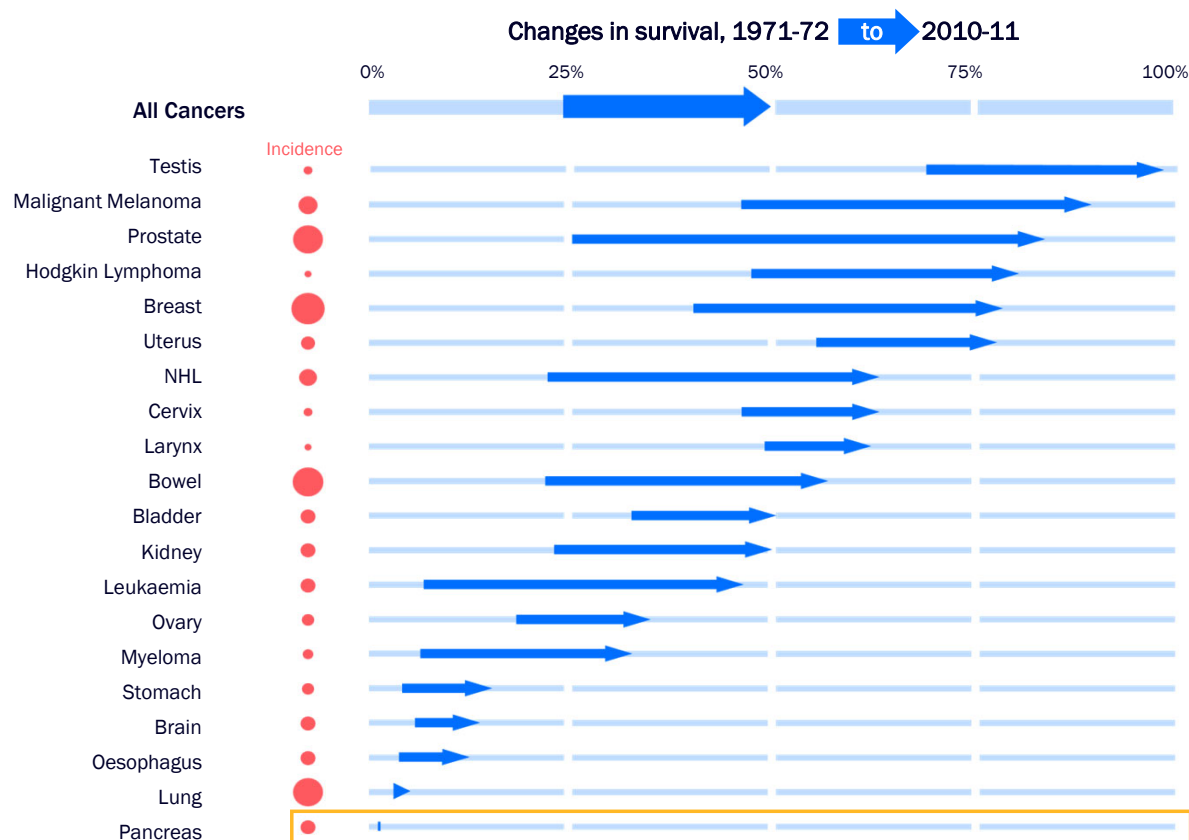
The information contained in this presentation is current as at July 2024.



A primer on pancreatic cancer



• An enhanced pancreatic cancer treatment finally at hand

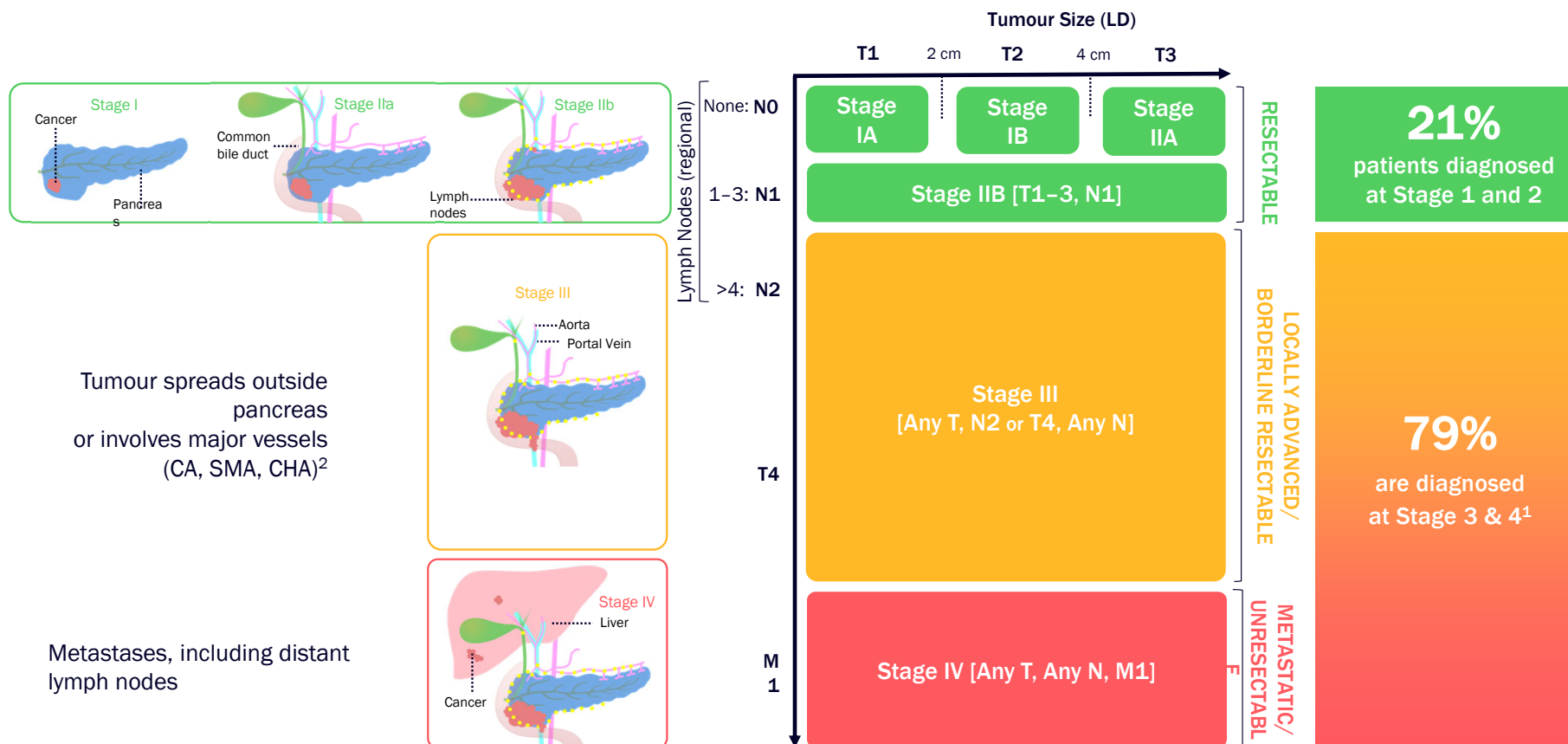


- The prognosis for pancreatic cancer patients has remained almost unchanged for over 40 years¹
- The reported five-year survival rate for the disease of 10%²

1. Cancer Research UK. www.cancerresearchuk.org/health-professional/cancer-statistics/survival/common-cancers-compared#heading-Three (accessed November 2021)

2. American Cancer Society. Cancer Facts & Figures 2021. <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2021/cancer-facts-and-figures-2021.pdf>

Clinical Stages of Pancreatic Cancer¹

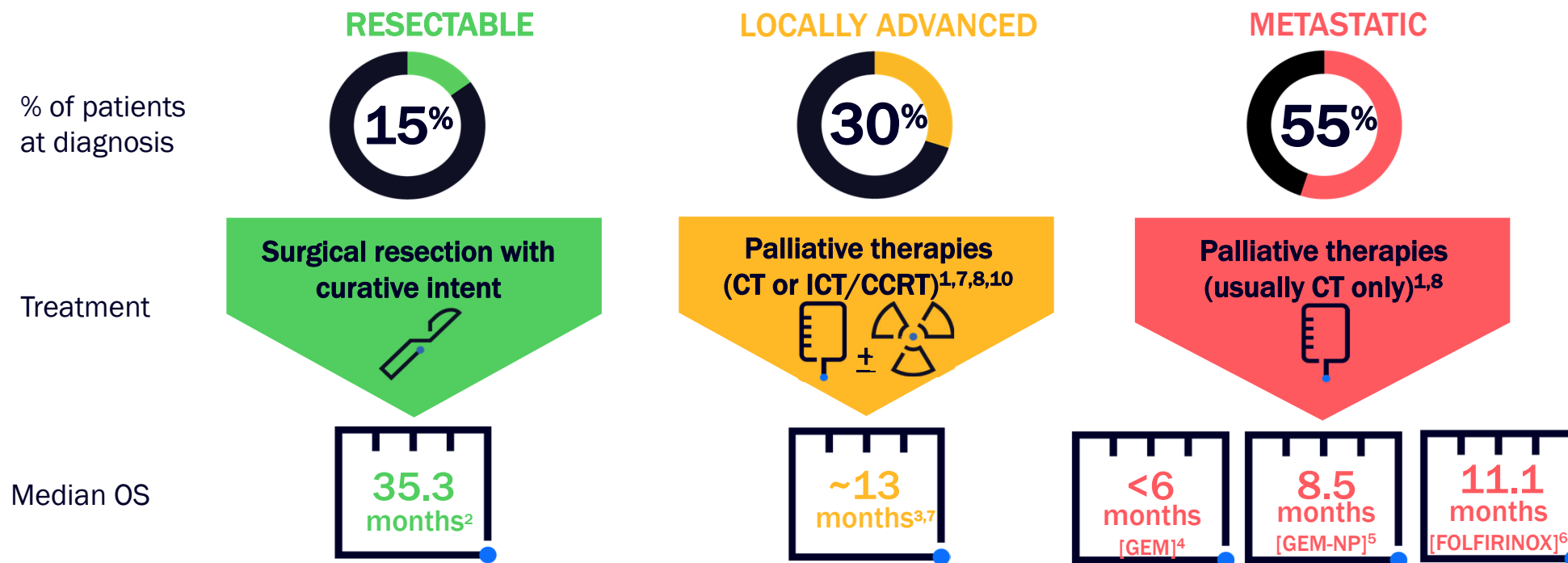


1. Image adapted from letswin.pc.org; AJCC, American Joint Committee on Cancer. Cancer Staging Manual, 8th Edition. Editors: Amin MB, Edge SB, Greene FL et al. 2018. Springer. (<https://www.macmillan.org.uk/cancer-information-and-support/pancreatic-cancer/staging-and-grading-of-pancreatic-cancer>) (accessed November 2021)

2. CA - Celiac artery; CHA - Common hepatic artery; SMA - Superior mesenteric artery

• Surgical Resection

The only potentially curative treatment for pancreatic cancer¹



30% of LAPC patients shows metastatic progression with 3-6 months^{9,10}

1. Ducreux M et al. Ann Oncol 2015; 26 (Suppl 5): v56-68.

2. Gemenetzis G et al. Ann Surg 2019; 270: 340-347.

3. Chang JS et al. Cancer Res Treat 2018; 50: 562-574 (suppl data).

4. Burris HA 3rd et al. J Clin Oncol 1997; 15: 2403-2413.

5. Von Hoff DD et al. N Engl J Med 2013; 369: 1691-1703.

6. Conroy T et al. N Engl J Med 2011; 364: 1817-1825.

7. Balaban EP et al. J Clin Oncol 2016; 34: 2654-2668.

8. National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Pancreatic adenocarcinoma. Version 1.2020.

9. Huguet et al. J Clin Oncol 2010.

10. Mukherjee et al, Lancet Oncol 2013.

10. CT - Chemotherapy; ICT - Induction chemotherapy; CCRT - Concurrent chemoradiation therapy



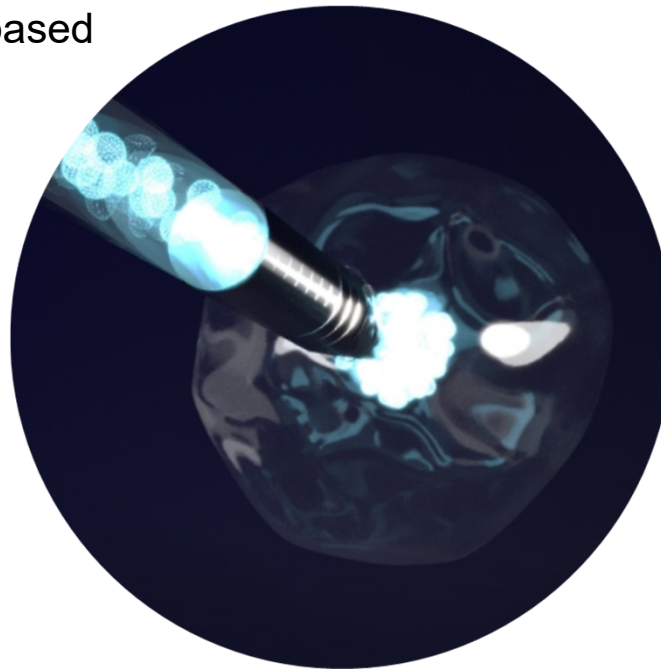
The OncoSil™ device



• OncoSil™ Device

OncoSil™ is intended for the treatment of **locally advanced unresectable pancreatic cancer**, in combination with gemcitabine-based chemotherapy

OncoSil™ is implanted directly into a pancreatic tumour via injection under **endoscopic ultrasound** guidance



OncoSil™ is a **single-use** brachytherapy device comprised of microparticles and a diluent

98% of all radiation is delivered within **81** days of injection ...

... causing damage to cancer cell DNA and **killing malignant cancer cell** and **no damage to surrounding tissue**



Validating OncoSil™ device's effectiveness



• PanCO study demonstrated positive safety and efficacy signals

Of the many encouraging outcomes from the PanCO study¹, four are particularly important:



Established safety profile:

No evidence suggesting any additional risk from using OncoSil™



90.5% of OncoSil™ treated patients had local disease control at 16 weeks, which was the primary efficacy measure of the study and was statistically significant compared to the pre-set hypothesis



Although all study participants were initially unresectable, 1 in 3 patients (33%) became eligible for resection after receiving OncoSil™, and nearly 1 in 4 patients (23.8%) underwent surgical resection with curative intent





There was a statistically significant reduction in tumour volume for patients who received OncoSil™, with 57% of participants having their tumour volume reduced by at least 50%

1. Ross PJ, Wasan HS, Croagh D 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. [https://www.esmopen.com/article/S2059-7029\(21\)00318-5/fulltext](https://www.esmopen.com/article/S2059-7029(21)00318-5/fulltext)


• TRIPP-FFX

An open-label, multi-centre, randomized study of **TaRgeted Intratumoural Placement of Phosphorous-32 (OncoSil™)** in addition to **FOLFIRINOX** chemotherapy versus **FOLFIRINOX** chemotherapy alone in patients with unresectable locally advanced pancreatic adenocarcinoma

- 

Objective To assess the safety and efficacy of OncoSil™ when given in addition to standard FOLFIRINOX chemotherapy for treatment of Locally Advanced Pancreatic Cancer – opportunity to provide **label expansion** into standard of care chemotherapy
- 


Location 19 sites in Spain, UK, Belgium, Australia and Italy with:


 - 12 sites open for recruitment
 - 31/80 subjects recruited to date
- 


Primary Endpoint Safety and Tolerability as determined by the Adverse Event profile
Local Disease Control Rate at 16 weeks

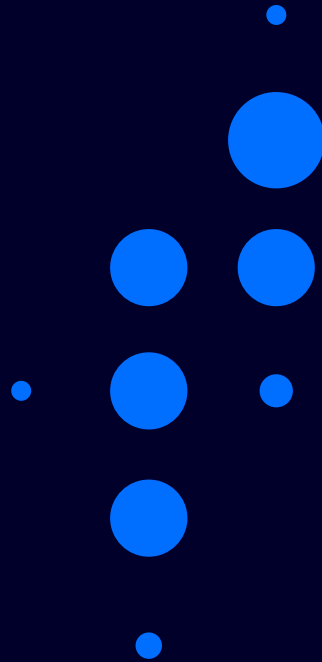
- **PANCOSIL** (Investigator Initiated Study)

Safety and feasibility of CT-guided percutaneous radionuclide therapy with the OncoSil™ device in patients with non-progressive locally advanced pancreatic cancer (PANCOSIL): an open-label, single-arm phase 1-2 feasibility study

 **Objective** 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. Successful completion enables OncoSil to **expand the user base to include Interventional Radiology**

 **Study Sites** Amsterdam UMC & Antonius Hospital Nieuwegein
1/2 sites initiated
6/20 subjects recruited

 **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



Corporate overview and leadership team



• Leadership team



Nigel Lange

Managing Director & CEO

30+ years experience in medical device industry

Served as Group COO and Interim Group CEO of Sirtex Medical



Douglas Cubbin

Non-executive Chairman

Experienced biopharmaceutical executive with over 30 years' experience in senior roles across varied industries.

Was a key member of Telix Pharmaceuticals (ASX:TLX) which completed IPO, raised \$270m in capital.



Gabriel Liberatore

Non-executive Director

Dr Liberatore is an experienced biopharmaceutical executive with over 25 years' experience. Until recently, he was the Group Chief Operating Officer at Telix Pharmaceuticals (ASX:TLX)



Peter Hall

To be Appointed

Non-executive Director

by the end of August 2024

London-based Australian financier, media proprietor and philanthropist. Founded investment firm Hunter Hall Investment Management in 1993, and acted as Chief Investment Officer and Executive Chairman during his 23 year tenure.

• Leadership team



David Turner

Head of Medical Affairs

40+ years experience in pharmaceutical, medical device and health technology industries



Henk Tissing

Director of Clinical Development

25+ years industry experience in oncology with pharmaceuticals and medical devices. Senior clinical development roles at Sirtex Medical, BTG, A-Z and Sanofi Aventis



Christian Dal Cin

Chief Financial Officer

Christian has over 20 years' experience with listed and private companies includes corporate secretarial, accounting and general management through The CFO Solution and previous roles.



Renzo DiCarlo

Head of Transformation

A proven nuclear medicine executive Renzo brings over 25 years' experience in therapeutic drugs and medical devices.



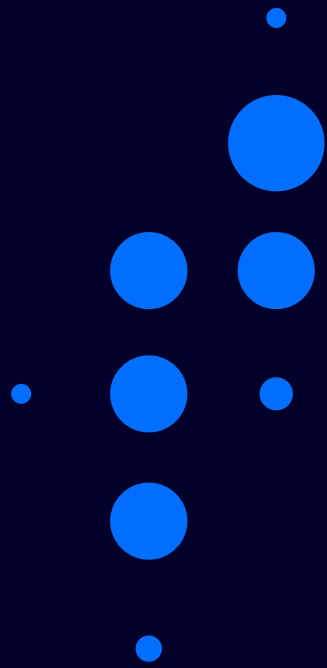
Dr Jon Bell

Chief Medical Officer

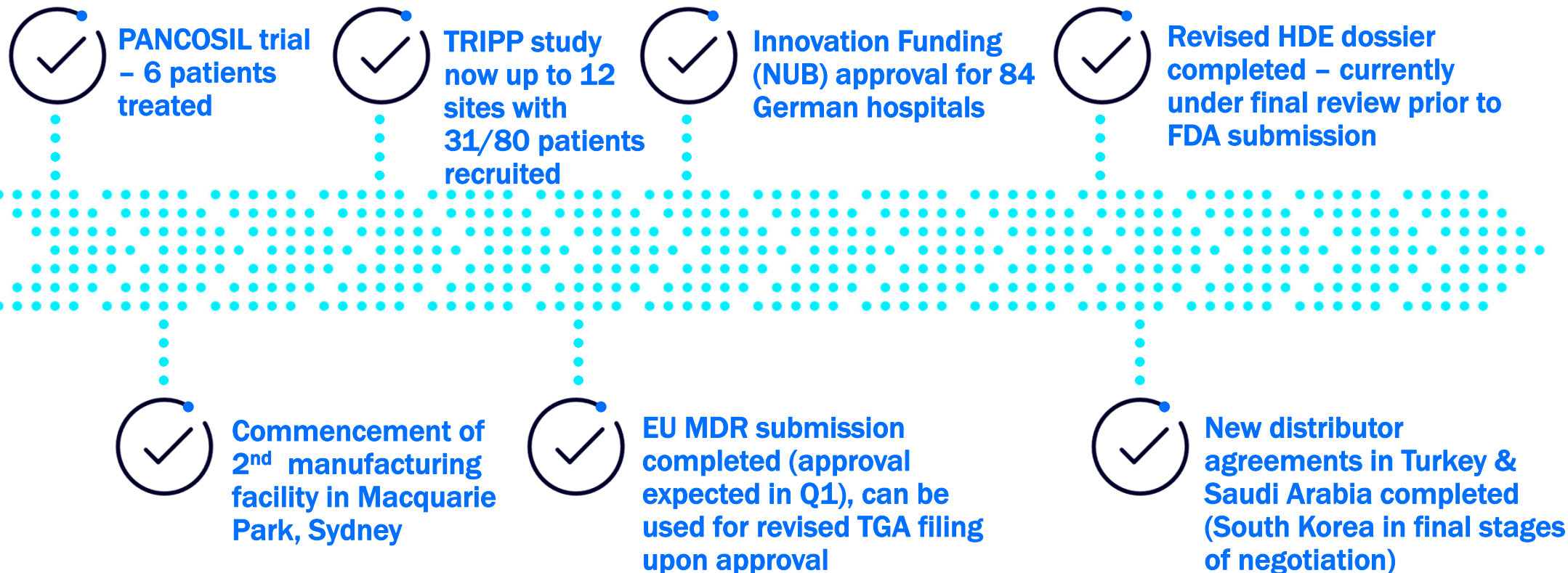
8+ years experience as an interventional radiologist and an internationally recognised expert in interventional oncology



FY 2024



• Achievements FY2024



1. HDE - Humanitarian Device Exemption
2. FDA - Food and Drug Administration
3. DCC - Distal cholangiocarcinoma (or bile duct cancer)



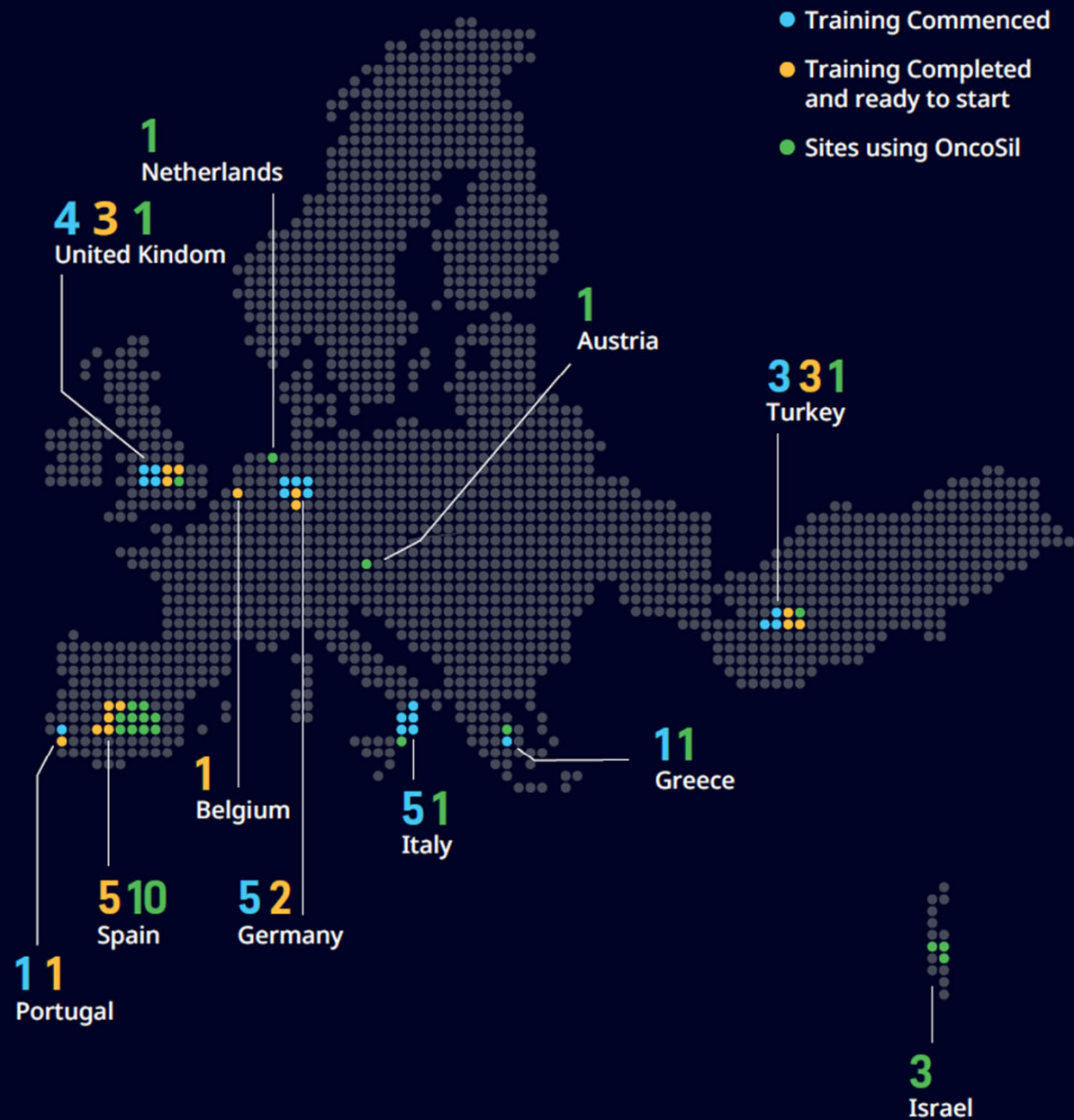
Commercialisation strategy & investment thesis



• Targeted commercialisation strategy deliverables

- G-BA progressed to commercial agreement
- FDA processes advanced
- EU MDR Approval
- Re-engage TGA for approval in Australia following MDR approval
- A steady uplift in the number of commercial treatments utilising OncoSil™ device
- Additional distribution agreements underway in several markets such as South Korea and selected Middle East countries
- A broadening and deepening of our geographic footprint

Sites undertaking OncoSil™
Device treatments continue
to grow



• The OncoSil™ device is now in early-stage commercialisation

The OncoSil™ device, an effective treatment for locally advanced pancreatic cancer, is now penetrating its already large and continually growing target addressable markets

- ✓ Many key components of commercialisation strategy are already in place (breakthrough device designation; market approvals in a steadily increasing number of countries/regions)
- ✓ The device is approved for sale in 34 countries
- ✓ A growing network of hospitals located across an expanding geographic footprint are treating patients with the OncoSil™ device
- ✓ OncoSil™ has converted patients with unresectable locally advanced pancreatic cancer to surgically resectable, transforming their prognosis and substantially extending survival¹
- ✓ Working towards innovation funding in Germany
- ✓ Further studies are now being progressed
- ✓ OncoSil's journey to commercialisation is being led by a highly experienced Board and Senior Executive team
- ✓ Market access and clinical development teams are working on multiple activities to expand the addressable market

1. Ross PJ, Wasan HS, Croagh D 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. [https://www.esmopen.com/article/S2059-7029\(21\)00318-5/fulltext](https://www.esmopen.com/article/S2059-7029(21)00318-5/fulltext)



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