

ASX Announcement

20 November 2024

Chairman's Address to Annual General Meeting

Sydney, Australia – 20 November 2024: Pancreatic cancer treatment device company OncoSil Medical Limited (ASX:OSL) ("OncoSil" or "the Company") is pleased to provide the Chairman's address to today's Annual General Meeting.

Chairman's address

On behalf of the entire Board of OncoSil Limited, it is my pleasure to welcome our shareholders to the Company's Annual General Meeting (AGM) for the financial year ended 30 June 2024.

The AGM is always a key event in our corporate calendar. It provides an opportunity for your Board to highlight OncoSil's achievements over the past year and update shareholders on the Company's future plans. Importantly, the AGM also gives you, our shareholders, the opportunity to ask questions of your Board about OncoSil's recent and future performance.

Our OncoSil™ single-use brachytherapy device achieved a host of commercialisation and validation milestones over the past 12 months.

Indicative of the great strides recently made in the OncoSil™ device's commercialisation journey, the number of doses used at commercial treatments over Q4 FY24 was up 78% on a previous corresponding quarter basis. This Q4 FY24 figure was also more than 2.5 times the average volume for the first three quarters of FY24.

At this point, I want to highlight the fact that the OncoSil™ device's FY24 milestones were not all numbers-specific. Many related to distribution agreements and approval processes that are critical to the successful delivery of our well-enunciated commercialisation strategy for the OncoSil™ device. Taken together, these achievements - some of which I will next cover briefly - saw our Company continue to penetrate a number of target addressable markets in Europe and the Middle East.

In November 2023, major Israeli health insurer Clalit General Health Services approved the OncoSil™ device as an appropriate treatment for locally advanced pancreatic cancer. This approval is a necessary first step ahead of any payments for OncoSil™ device treatments in this important Middle East market.

Early December 2023, saw our Company make an initial foray into Greece, with the first two commercial treatments involving the OncoSil™ device occurring in that country.

In February 2024, we laid the groundwork for our eventual entry into Türkiye, with the signing of an agreement to market and distribute the OncoSil™ device in that large EU country.

Early April 2024 saw the first two Austria-based patients receive treatments involving the OncoSil™ device.

In late FY24, we progressed our plans to penetrate the lucrative Saudi Arabian market, with the signing of an exclusive 3-year distribution agreement. This deal gives us an entrée to a key Middle Eastern country that boasts a large and growing healthcare sector with first class infrastructure.



Subsequent to the end of our FY24, our entry into the huge German market received a massive boost, with OncoSil informed that the much-awaited German Federal Joint Committee or G-BA approvals had been granted. Our CEO and Managing Director Nigel Lange will be providing more detail on the significance of this approval in his FY24 AGM presentation, which will follow my Address.

I am happy to say that OncoSil has achieved a host of additional commercialisation strategy deliverables in the post-FY24 period, including:

- The first surgical resection of a pancreatic tumour in the patient commercially treated with the OncoSil™ device occurring in Türkiye, just months after we signed a distribution agreement in that country.
- Continued penetration into the Spanish market, with the successful completion of the 30th treatment involving the OncoSil™ device.
- Further penetration of the Italian market.
- The signing of three exclusive distribution agreements to market and distribute the OncoSil™ device, one each for the Nordics region, the Gulf Cooperation Council countries and Egypt.

On top of our commercialisation strategy successes, we also progressed a number of seminal studies that will further validation of the effectiveness of the OncoSil™ device and enhance its efficiency of use.

Two key trials involving the OncoSil™ device were materially advanced over FY24.

Late November 2023 saw the first patient treated in the Netherlands-based PANCOSIL Investigator Initiated Clinical Trial. By late FY24, five patients had been treated with the device in this Trial. Fast forward by several months, and by early FY25, the PANCOSIL Investigator Initiated Trial has reached 70% of patients recruited, with the 14th patient treated.

Another key trial, the TRIPP-FXX clinical study, also got underway in earnest towards the end of our FY24, with its first patient treatment with the OncoSil™ device. At today, we have completed 59% of the target patient recruitment in the TRIPP-FFX clinical trial.

While all these achievements were being delivered, OncoSil Medical successfully undertook some capital raising initiatives in the second half of FY24 that materially strengthened our balance sheet. We successfully completed a Placement and Entitlement Offer during the year, which saw the Company raise around \$6.8 million before 30 June 2024, with a further \$0.33 million raised in July 2024.

Subsequent to the end of our FY24, late July 2024 saw an institutional investor enter OncoSil Medical's share registry via a \$2.7 million placement.

We then completed a \$7.0 million placement to sophisticated and professional investors in October 2024. At this time, we also set in motion a Share Purchase Plan offer to raise approximately \$1.0 million (before costs) from eligible shareholders.

Before I pass you over to our CEO and Managing Director Nigel Lange, I want to take this opportunity to say a big thank to all our major stakeholders for their continued support over the past 12 months. To my fellow Directors, as well as our management and staff, I thank you for your ongoing commitment to the successful delivery of OncoSil's development and commercialisation strategy over the past year.

And last but not least, I want to thank our shareholders for their patience and continued support as the OncoSil™ device's commercialisation journey continues to be steadily progressed.



Authorisation & Additional Information

This announcement was authorised by the Chairman 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 12th most common cancer in men and the 11th 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 survival¹.

The OncoSil™ device delivers a targeted intratumoural placement of Phosphorous-32 (32P) 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/

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



AGM Presentation

November 20, 2024

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 fillings 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.

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 20 November 2024.

Executive Summary



Commercialising targeted radiotherapy for pancreatic cancer

- OncoSil Medical is commercialising the OncoSil[™] device, an implanted device (brachytherapy) delivering targeted radiation (³²P) to pancreatic tumours In Oct-24, OncoSil Medical treated its 200th 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 combinations¹
- 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 competition⁴

- 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 2035²
- 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:³
 - ✓ 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

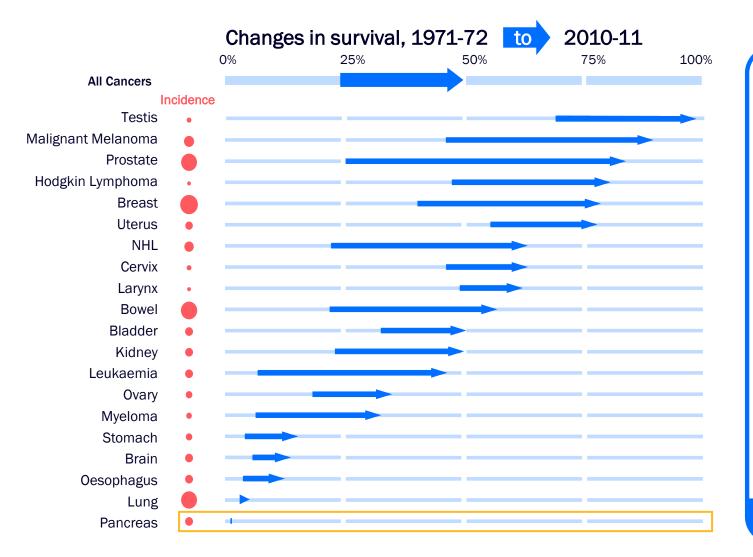
- Received UKCA Certificate which includes the removal of all existing post-market restrictions in the UK (OSPREY registry)
- 70% Recruitment achieved in landmark PANCOSIL study (a groundbreaking delivery method for OncoSil™ device)
- 59% Recruitment achieved in TRIPP-FFX study (to expand OncoSil[™] 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, Switzerland¹
 - 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 (20 CY25)

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 survival²
- Lower survival rate than any other cancer³
- The number of cases and deaths both estimated to increase by 40% before 2035³

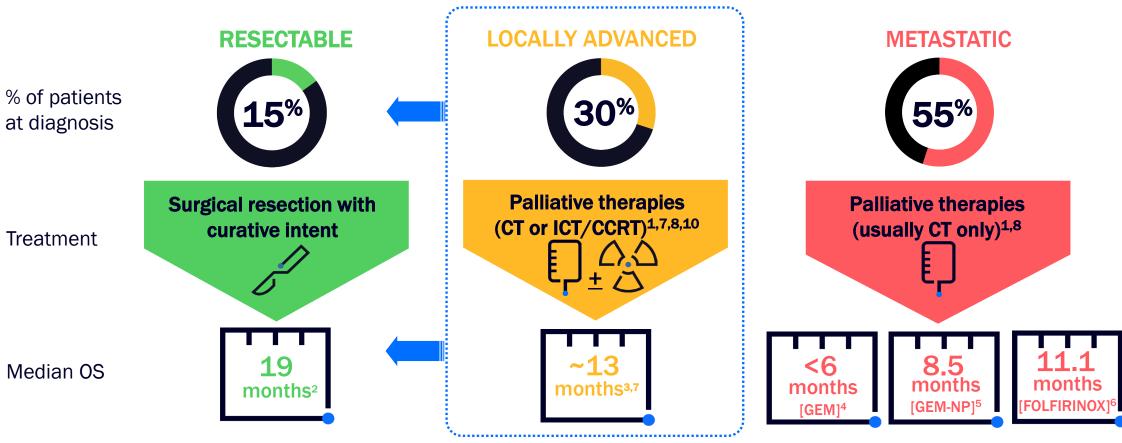


New therapeutic options urgently needed

Pancreatic Cancer Stage at Diagnosis



Surgical resection remains the only potentially curative treatment for pancreatic cancer¹



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

OncoSil[™] 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[™] 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[™] is a single-use brachytherapy device comprised of microparticles imbedded with ³²P and a diluent

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 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% reduction²



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



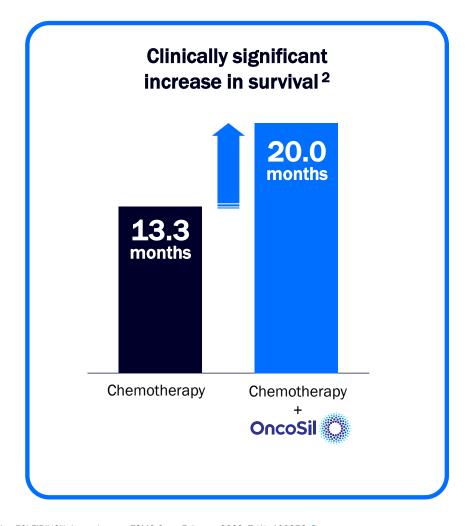
Significantly increased survival in those receiving OncoSil[™] compared to chemotherapy alone in a propensity score analysis: median overall survival 20.0 vs. 13.3 months (p=0.001), with 3.7 months (+32.3%) longer restricted mean survival time (RMST) at 24 months from starting treatment ²



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 ²



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



OncoSil™ plus Standard-of-Care Chemotherapy



At least doubling the number achieving surgical resection or downstaging compared to chemotherapy alone^{1,2}



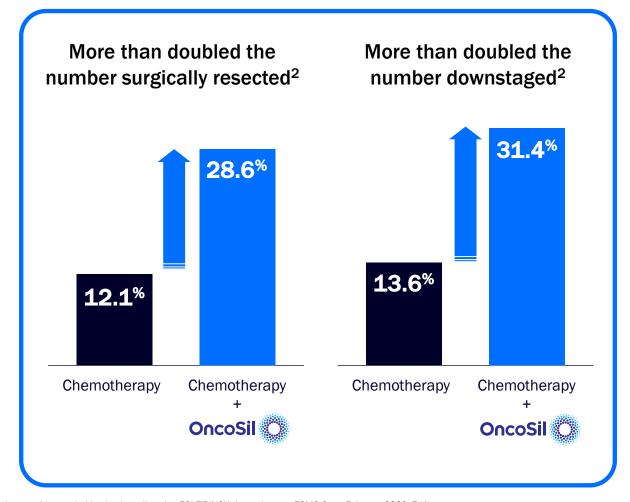
Around 1 in 4 patients (23.8% in PanCO; 28.6% in the Propensity Score analysis) with unresectable LAPC receiving OncoSil[™] plus chemotherapy underwent surgery with curative intent, compared with resection rates of 12.1% of patients receiving chemotherapy alone in the Propensity Score analysis ^{1,2}



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 1,2



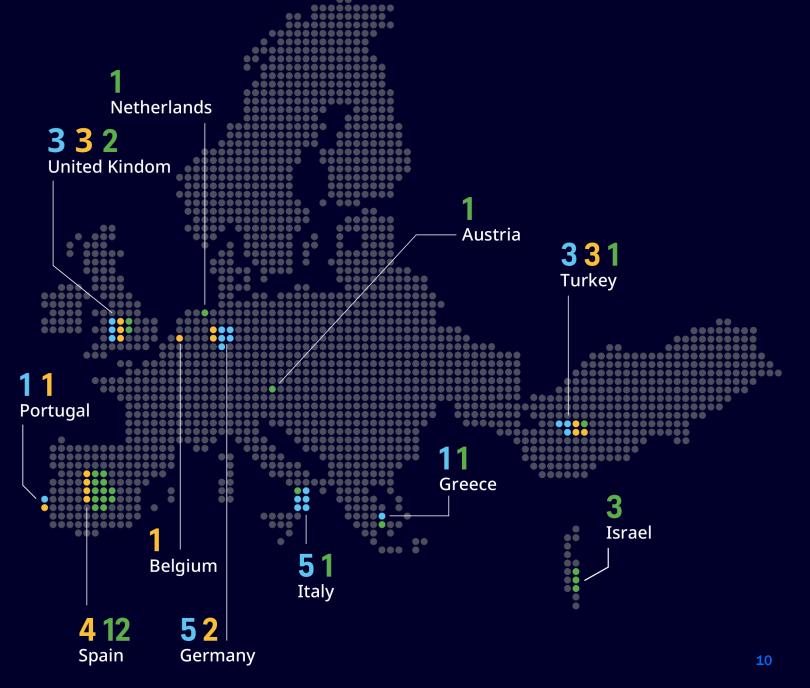
6 of the 10 resected patients in the PanCO study remained alive, 5 having no evidence of disease, at 32.0 months median follow-up from enrolment in the study ¹



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. ¹	Locally Advanced Pancreatic Cancer ²	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			
Total (Existing)	79,172	23,752	~588			
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			
Total (New)	54,620	16,386	~401			



OncoSil[™] device remains at the earlystage 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 (³²P) 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	 70% recruitment achieved (14/20) Target Study completion Q1 2025 Regulatory submission target of Q2 2025 Added to Label and targeted commercial launch in EU and UK markets in 2H25 	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	 59% recruitment achieved (47/80) Target completion Q3 CY25 Target Regulatory submission Q3/4 CY25 Added to Label in all approved jurisdictions H1 CY26 	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 Chalingiocarcinoma - dCCA) For approval by US FDA under Human Device Exemption (HDE)	 Discussions remain ongoing and constructive with US FDA OncoSil is preparing additional data to support HDE application 	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.	 G-BA approval received Oct-24 Procedural finalisation from Ministry of Health Q1 2025 Expected completion date of trial Q4 CY27 	Public insurance reimbursement for OncoSil™ device in Germany for trial participants. Opportunity for participating hospitals to receive reimbursement for patients nor participating in trial.



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





Outlook



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

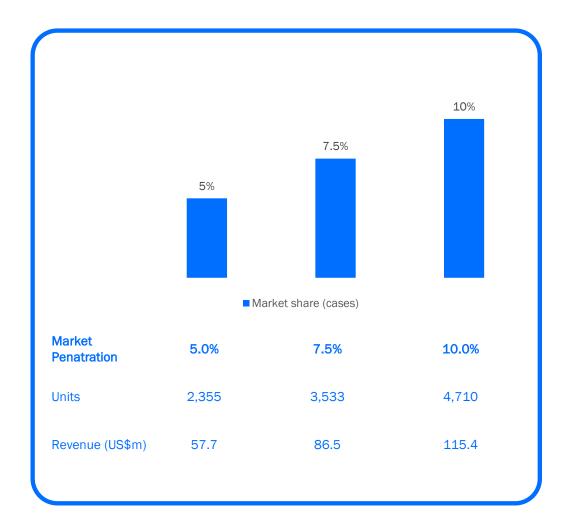
OncoSil[™] has an aspirational target of 5–10% market penatration by CY29 in existing and near-term target markets implying up to 4,710 units p.a.

Label expansion activities enhancing market access including:

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



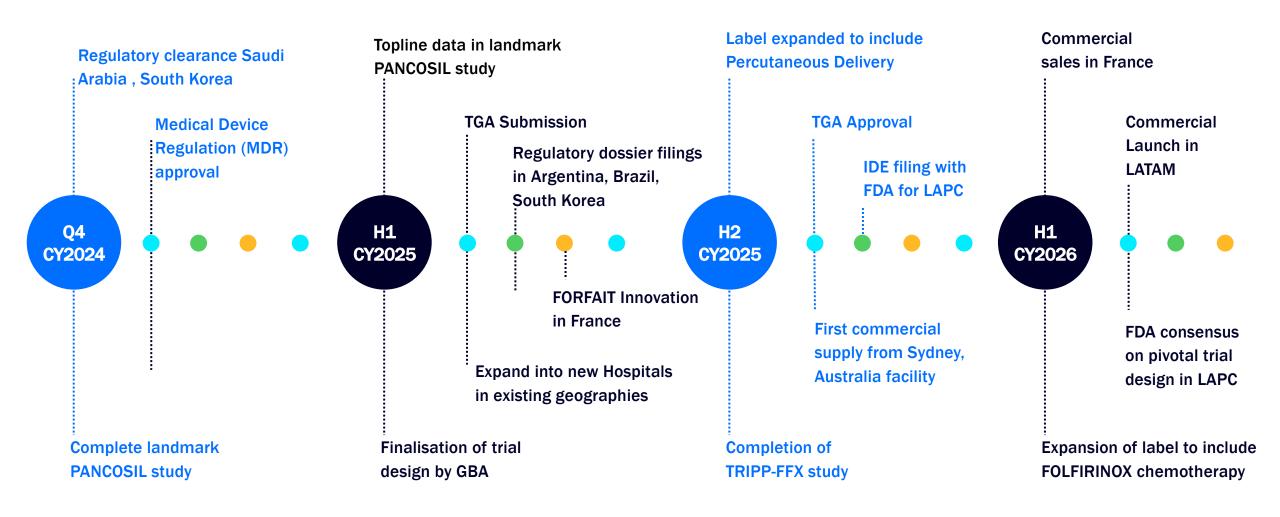
Is expected to significantly accelerate current aspirational volume targets



Upcoming Milestones



Significant catalysts over the next 24 months





AGM Update

Renzo DicarloOperations and R&D

November 2024

Targeted Approach • Positive Impact







- Master Validation Plan being developed
- R&D target schedule has been developed with Ansto, Lucas Heights
- Cyclotek facility is now in validation phase and all major components have been installed





"making radiopharmaceuticals accessible"

Macquarie Cyclotek site

- Regulatory approval will be sought by Q2 2025 for the Macquarie Cyclotek site
- Site will be ready to receive and measure Hot Target in Nov 2024
- New dispensing doses of 50, 100, 150 and 200 Mbq will be set up for therapy
- Gamma Spec Quality methods are in development





Quality

- Cyclotek ISO 13485 process to start in Q4
 2024 with the goal to complete certification by H1 2025
- Addition to Oncosil supplier list for ISO 13485 to start Q1 2025











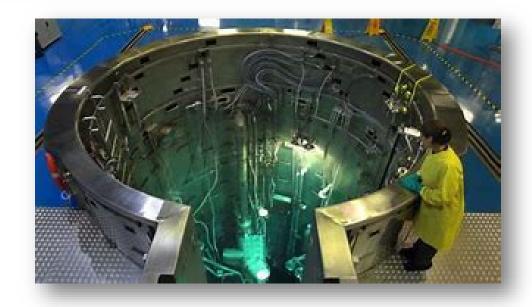
ANSTO contract negotiations have been completed in Oct 2024 for target supply



ANSTO has agreed to increase reactor spots when needed to meet the growing Oncosil R&D and commercial supply



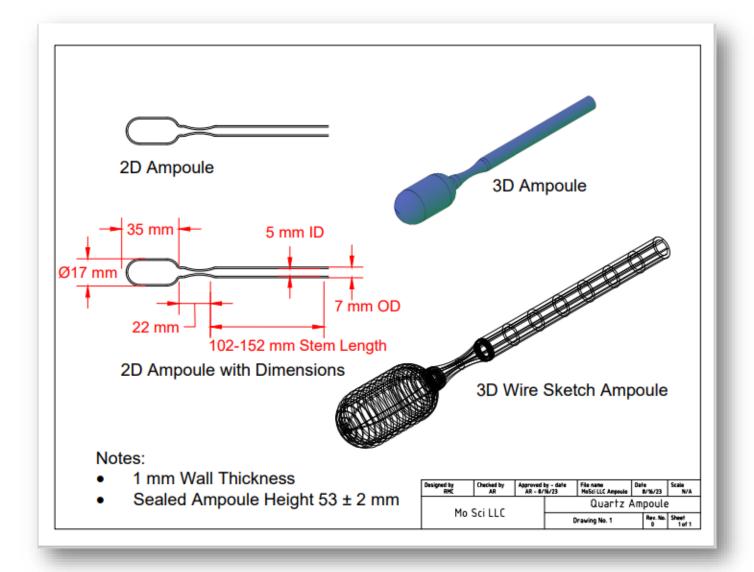
The ANSTO agreement will be signed in Nov 2024



22 • AGM Update

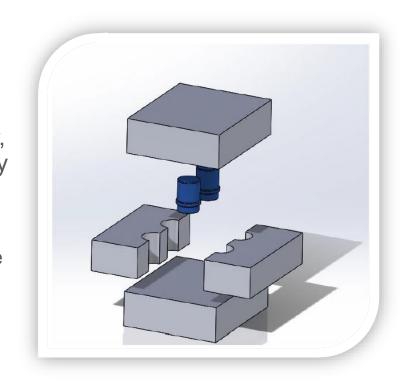


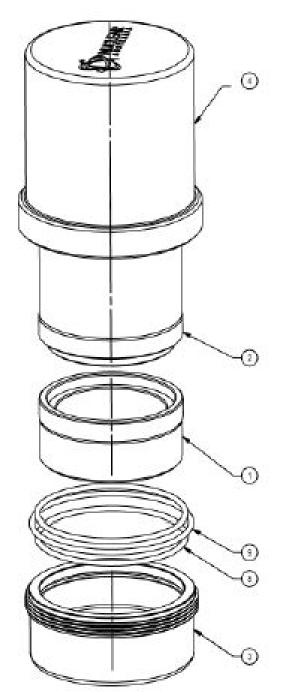
- Innovative quartz ampoule design complete
- Mo-Sci in Missouri has been engaged for regular supply of the new quartz stock vessel
- The new ampoule targets will be irradiated at ANSTO in Nov 2025

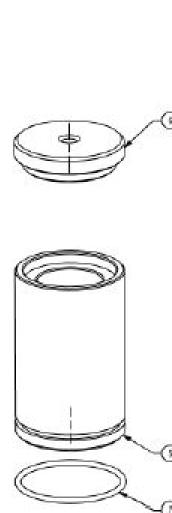




- Nuclear Australia has been engaged to produce a lighter, more environmentally friendly Type A finished final product package
- Marketing considerations are currently being applied









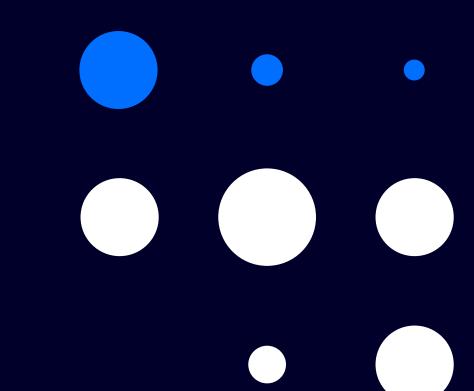
Nigel Lange

CEO & Managing Director

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Learn more about OncoSil Medical:

- Website
- ASX announcements
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