



oncosil

MEDICAL
ASX.OSL

Investor Presentation

*Advancing Pancreatic cancer treatment
Transforming the prognosis*

May 2020



***Commercialising a breakthrough implantable
radiotherapy treatment for pancreatic cancer***

Executive Summary

OncoSil Medical is a commercial-stage medical device company pursuing targeted radiotherapy for pancreatic cancer	<ul style="list-style-type: none">• Implanted device (brachytherapy) delivers targeted radiation to pancreatic tumour• In combination with chemotherapy it has clinically proven to double survival times and reduce tumour size• Platform technology can be leveraged into other indications (Bile duct cancer, liver)
>US\$3bn global addressable market with no competition¹	<ul style="list-style-type: none">• Global patient population of ~130k p.a at indicative US\$25k per device• No other approved products and not aware of any competition in advanced development• Extensive Patent coverage across all key geographies out to 2024 for EU & RoW and 2028 for US
Now ready to commercialise	<ul style="list-style-type: none">• Approved for sale in over 28 countries via CE Mark (received April 2020)• First sales in EU & UK expected in 2H20 (COVID-19 permitting)• Pending regulatory approvals in Australia, NZ, Hong Kong, Singapore• Breakthrough designation from FDA and pursuing US approval via Humanitarian designation in 2H20• Manufacturing complete for commercial roll out and can be scaled rapidly for anticipated growth• Highly regarded Board & Management with extensive commercialisation experience – ex Sirtex, Cochlear & big pharma
Potential for significant revenues and segmental profitability² in CY21 and beyond	<ul style="list-style-type: none">• High gross margins when at scale, with a low fixed cost base• Concentrated and well defined hospital customer base – only modest salesforce required• R&D time and cost sunk over past 5 years in excess of A\$50mn
Raising up to A\$19m via Placement and Entitlement Offer at A\$0.09 per share	<ul style="list-style-type: none">• Funds raised will be to support sales roll out in the UK, EU and ASEAN regions• Accelerate both commercialisation of Bile Duct Cancer in the US (post approval) and to bring forward the start of the US Pancreatic clinical trials

Notes.

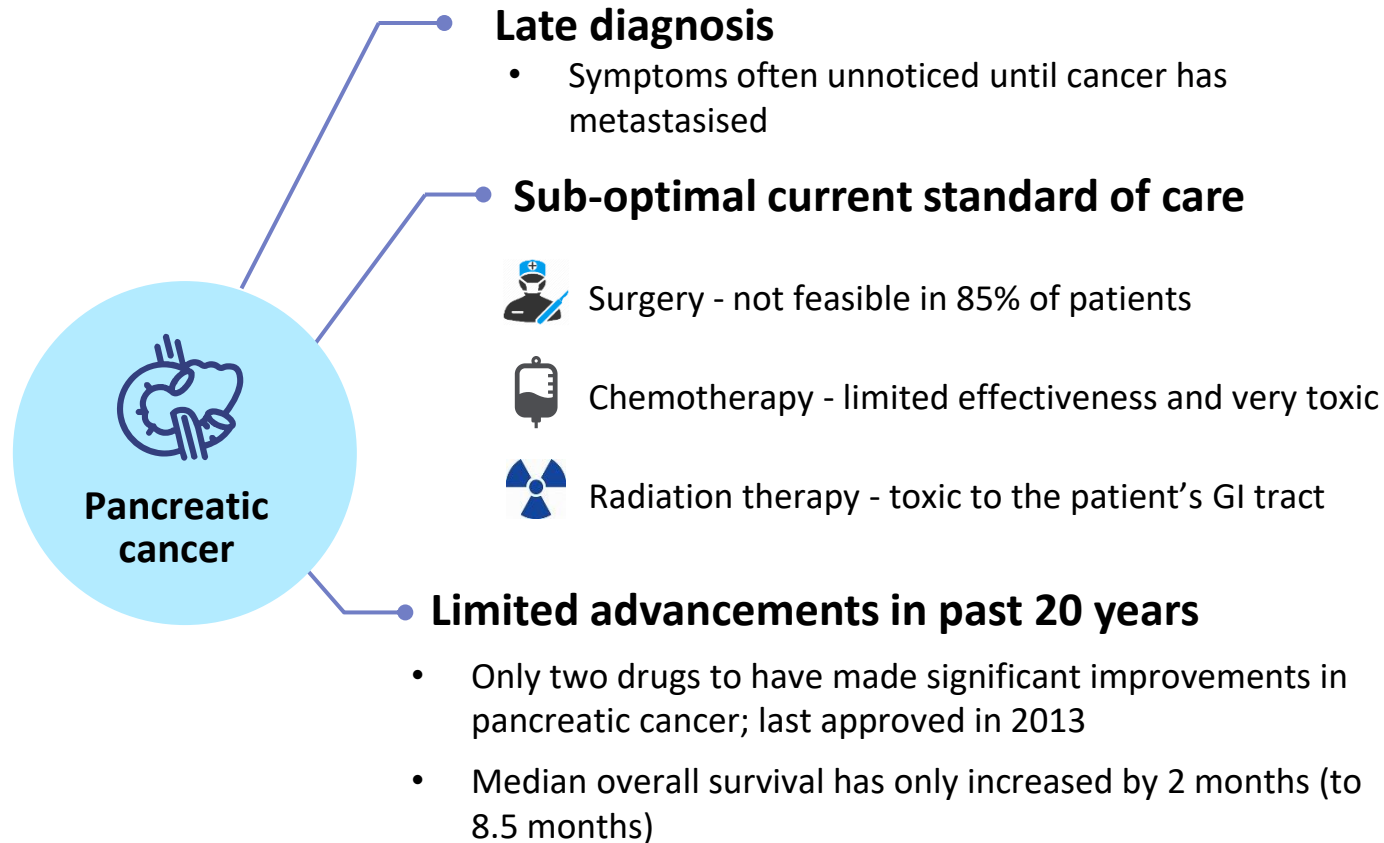
1) Refers to competition in Brachytherapy treatment

2) Segmental profitability excludes corporate costs (e.g. US regulatory and clinical trial costs); COVID-19 dependent

Treating Pancreatic cancer is challenging and difficult

Existing treatments for pancreatic cancer are ineffective...

...resulting in very poor survival rates¹



~8.5 months
Overall median survival

<5% chance
Reaching 5-year survival mark

Notes.

(1) Loehrer PJ et al. J Clin Oncol 2011Nov 1;29 (31) 4105-12

The OncoSil™ device provides a unique and effective solution

Radiation therapy delivered directly into the tumour



The Approvals

- CE Mark approval
- Breakthrough designation in EU, UK and US
- Classified as Active Implantable Medical Device in EU, AUS
- Classified as Class III in US



The Trials

- 6 clinical studies completed to date
- All yielding positive results on tolerability, safety and efficacy
- Results from PanCO trial underpinned CE Marking



The Mechanics

- Utilises radioactive microparticles containing a pure beta emitting isotope (^{32}P)
- Microparticles implanted directly into a tumour via EUS, designed to deliver an absorbed dose of 100Gy
- Single use device that remains in the tumour
- 98% of the radiation delivered within 81 days



The PanCO results

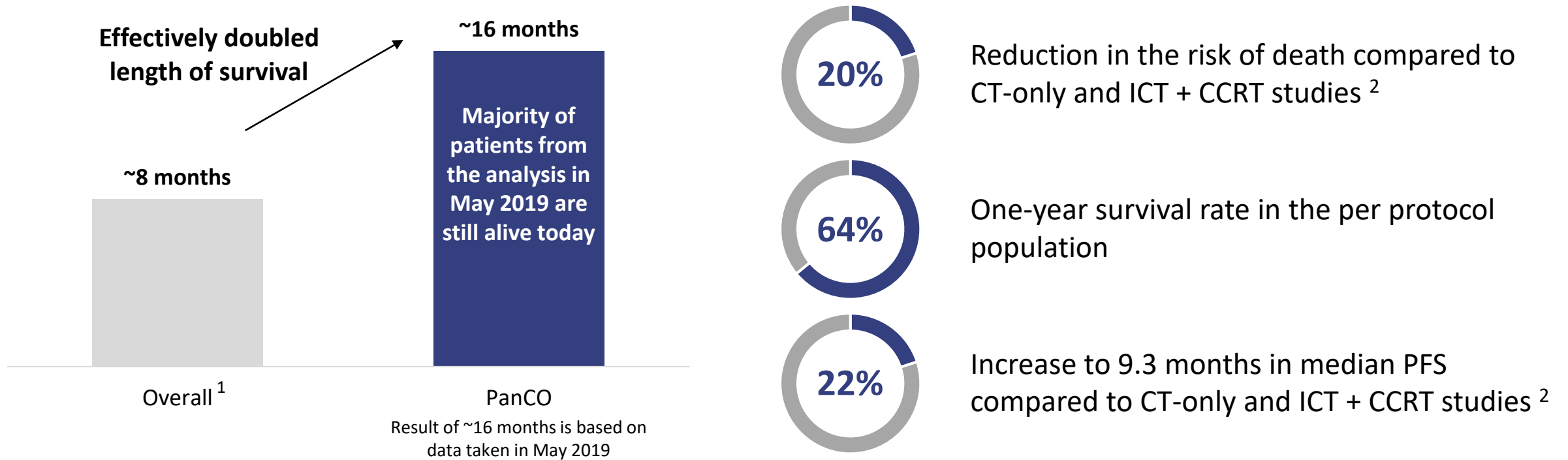
42 participants

See appendix

- ✓ Excellent Local Disease Control
- ✓ Prolonged Overall Survival
- ✓ Encouraging rate of Surgical Resection with Curative intent
- ✓ Higher Disease Control Rate
- ✓ Tumour reduction
- ✓ Prolonged Progression Free Survival

Technology backed by a body of strong clinical evidence

OncoSil™ has clinically proven to prolong median overall survival in LAPC patients



Majority of the cohort from the PanCO study is still alive today - survival length is expected to be even longer than 16 months

Notes.

(1) Loehrer PJ et al. J Clin Oncol 2011Nov 1;29 (31) 4105-12

(2) LAPC = Locally advanced pancreatic cancer; CT = Systemic Chemotherapy; ICT = Induction Chemotherapy; CCRT = Consolidated Chemotherapy

Compelling PanCO results showing clear evidence of downstaging

OncoSil™ converts inoperable patients to operable, extending survival and quality of life significantly

What is downstaging?



The event of decreasing the size of your tumour and shrinking the cancer



Sufficient downstaging can lead to patients becoming eligible for surgery

Why is it important?

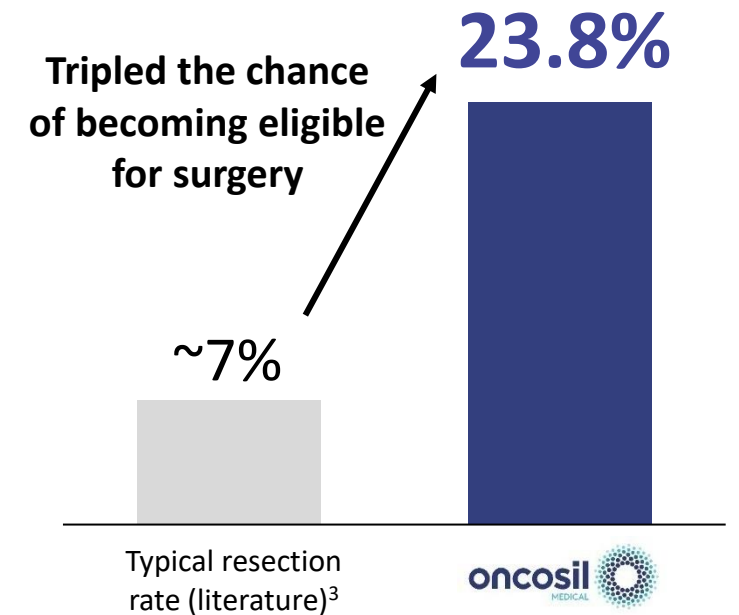
Typical survival lengths

Without surgery ~9 months ¹

vs

With surgery ~3 years ²

What did PanCO trial show?



Notes.



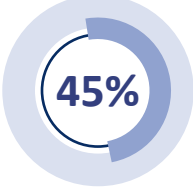
(1) Hammel, Pascal et al. Effect Of Chemoradiotherapy Vs Chemotherapy On Survival In Patients With Locally Advanced Pancreatic Cancer Controlled After 4 Months Of Gemcitabine With Or Without Erlotinib. JAMA 315.17 (2016): 1844

(2) Gemenetzis, George et al. Survival in Locally Advanced Pancreatic Cancer After Neoadjuvant Therapy and Surgical Resection. Annals of Surgery 2019; 270: 340-347

(3) Allerdice, Stephanie et al. Naïve Indirect Treatment Comparison of PanCO, a Pilot Study of OncoSil P-32 Microparticles Combined with Gemcitabine + Nab-Paclitaxel or FOLFIRINOX Chemotherapy, Versus Standard-of-Care Treatment in Unresectable Locally Advanced Pancreatic Cancer; Abstract World Congress GI Cancer, 2020 (in press)

Significant market opportunity for OncoSil to become standard of care

There are more than 50k locally advanced pancreatic cancer (LAPC) cases p.a. in EU & UK ¹

	Disease prognosis	Current treatment	OncoSil solution
<i>Future focus</i>	 15% Resectable	Surgery	OncoSil™ could be used to downstage tumours prior to surgery to improve surgical outcomes
<i>Current focus</i>	 40% Locally Advanced	Chemotherapy Radiation therapy	OncoSil™ provides treatment to shrink tumours, reduce pain, downstage to surgery and prolong survival
<i>Future focus</i>	 45% Metastatic	Chemotherapy	Unlikely to benefit overall survival but OncoSil™ may be used to control tumour growth, alleviate pain and improve quality of life



Promising opportunity to become the standard of care



- ✓ A form of radiation therapy, to be used in combination with chemotherapy
- ✓ More concentrated radiation compared to external beam radiation
- ✓ Safer use than external beam radiation as it does not impact healthy tissue

Notes.

(1) GLOBOCAN 2018: Estimated Cancer Incidence Worldwide in 2018 (IARC/WHO)

Highly attractive and scalable operating model for commercialisation



No competitors¹

- Patented technology that is difficult to reverse engineer
- There are no similar, competing products commercially available or in development, as supported by the breakthrough designation



Low cost base and moderate salesforce required

- High operating leverage anticipated through economies of scale in the long-term
- Nature of sales process and ongoing clinical data evidence means only a modest salesforce required to train key sites and increase penetration



Manufacturing capabilities in place and highly scalable

- End-to-end manufacturing capabilities and logistics already in place and able to meet commercial launch quantities
- Manufacturing capacity highly scalable



Platform technology applicable to other indications

- Platform technology applicable to multiple indications and tumour types, outside of pancreatic cancer
- Potential for further economies of scale

Notes.

1) Refers to competition in Brachytherapy treatment

OncoSil's commercialisation strategy currently in full swing

Clear focus on first sales in Europe and entry into other markets



Targeting a >US\$3bn, global unmet need in pancreatic cancer treatment

OncoSil's market opportunity for LAPC:



Target market	Commercialisation status	Pancreatic cancer incidences p.a ¹	Locally advanced pancreatic cancer ²	Market opportunity (USD) ³
UK (launch market)	Approved to sell	11,374	4,550	~\$115m
European Union	Approved to sell	88,631	35,450	~\$890m
Singapore	Approval pending in 2020	855	340	~\$9m
Hong Kong ⁴	Approval pending in 2020	766	310	~\$8m
ANZ	Australia – Approval anticipated in 2021 NZ – Yes	4,298	1,720	~\$40m
China	Developing regulatory pathway to approval, designing trials Commercialisation via strategic partnerships	116,291	46,520	~\$1,160m
Japan	Commercialisation via strategic partnerships	43,119	17,250	~\$430m
United States	Breakthrough designation received, designing PMA study Targeting approval 2022/2023	50,846	20,340	~\$500m

Notes.

(1) GLOBOCAN 2018: Estimated Cancer Incidence Worldwide in 2018 (IARC/WHO)

(2) Based on LAPC cases equating to 40% of all pancreatic cancer cases; (3) Based on OncoSil list dose pricing of US\$25,000

(4) Hong Kong Cancer Registry, Hospital Authority 2017. Accessed from <https://www3.ha.org.hk/cancereg/allagesresult.asp>

LAPC target market size is ~US\$3.2bn p.a

Europe – clear path to first revenues

Step by step plan to achieving first revenues

Clinical trials and evidence development

- ✓ Conducted PanCO clinical trial which underpinned CE Mark
- ✓ Increased awareness and buy-in through results and ongoing publications
- ✓ Support of key opinion leaders in EU and presented at all key conferences

Manufacturing and supply chain

- ✓ Manufacturing capacity, supply chain and logistics in place and validated

Regulatory approvals

- ✓ Obtained CE Mark in April 2020

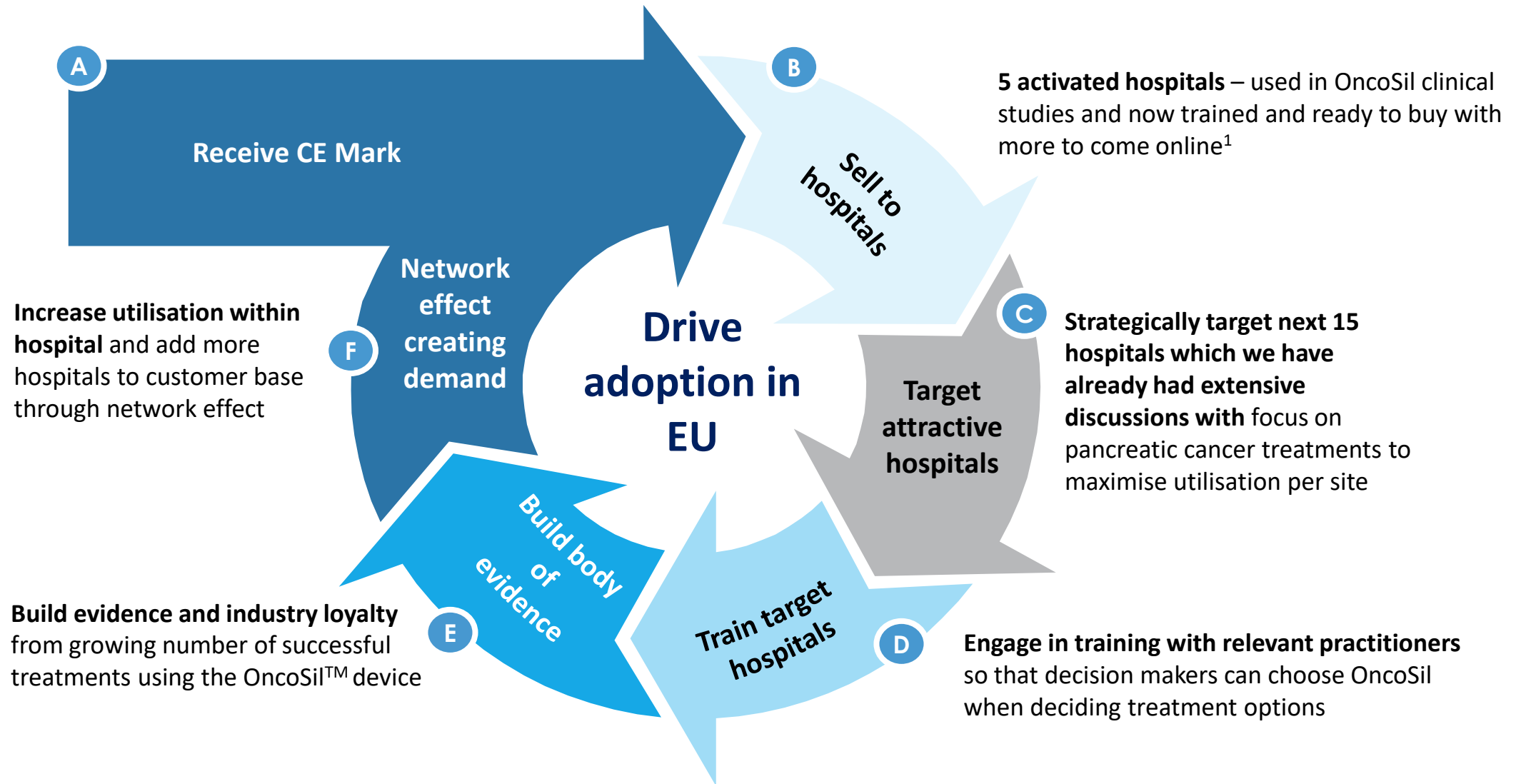
First Revenues¹

- ✓ Focus on top 20 hospital sites – already set up in 5, close relationship and extensive discussions with other 15
- ✓ Focus is on winning and activating large key hospitals with a small and focused sales team
- ✓ Once activated, we expect hospitals will quickly move all eligible pancreatic patients onto the device
- ✓ We expect strong network effect and exponential sales growth once leading centres are activated

Notes.

(1) Launch preparation is currently delayed due to the COVID-19 pandemic, with limited hospital access causing disruptions in new site initiation, training, shipping and logistics.

Europe – repeatable sales model to increase penetration



Notes.

(1) Launch preparation is currently delayed due to the COVID-19 pandemic, with limited hospital access causing disruptions in new site initiation, training, shipping and logistics.

US – Primary focus on Pancreatic but scope to expand into new indications

Potential to expand into new indications driving greater economies of scale

	Pancreatic Cancer	Bile Duct Cancer
Market opportunity	US\$500mn p.a ^{1,2}	US\$80mn p.a ³
Route to US entry thus far	<ul style="list-style-type: none">✓ August 2016: Investigational Device Exemption (IDE) granted by FDA✓ March 2020: Rare Breakthrough Device designation granted by FDA, successfully meeting its strict criteria	<ul style="list-style-type: none">✓ December 2018: Humanitarian Use Designation (HUD) granted by FDA✓ February 2020: Successfully agreed with FDA that PanCO data could be used as predicate for dCCA
Forward plan	<ul style="list-style-type: none">□ Now: Working closely with FDA to optimise the Pre-market approval (PMA) evidence development and clinical trials	<ul style="list-style-type: none">□ Now: HDE Submission planned for Q2 2020 HDE approval will mean right to sell in US 2021

Primary focus

Expansion into new indications

Notes.

(1) GLOBOCAN 2018: Estimated Cancer Incidence Worldwide in 2018 (IARC/WHO)

(2) Based on OncoSil list dose pricing of US\$25,000 and pancreatic cancer target market of 40% of incidences

(3) Based on OncoSil's target indicative list dose pricing of US\$50,000 and the incidence of distal cholangiocarcinoma in the US

Experienced Board of Directors with commercialisation experience



Dr Chris Roberts AO

Chairman

- 40+ years experience in medical innovation
- Served for 11 years as CEO of Cochlear Limited
- BE (Hons), PhD, DSc (Macq), Hon DSc (UNSW), FTSE, FAICD, Hon FIEAust
- PluS Alliance Professor appointed across UNSW, King's College London and Arizona State University



Dr Roger Aston

Non Executive Director

- Seasoned biotechnology entrepreneur with extensive experience serving on boards of biotechnology and pharmaceutical companies
- Former CEO of Mayne Pharma Group, Pitney Pharmaceuticals Ltd, pSiMedica, pSiOncology, Peptech Ltd and Cambridge Antibody Technology



Mr Michael Bassett

Non Executive Director

- 25+ years experience in capital markets and investment banking, with a focus on small-cap ASX-listed companies
- Served as a Portfolio Manager for Regal Australian Small Companies Fund and held a senior management role with Credit Suisse's Institutional Equities business
- B. Econ, AICD



Dr Martin Cross

Non Executive Director

- Highly regarded pharmaceutical executive with 30+ years experience
- Served as Chairman of Medicines Australia, Generics Medicine Industry Association and Pharmaceutical Industry Council
- B.SC (Hons) & PhD (Aberdeen), FAICD

Strong clinical and commercial pedigree in leadership team



Daniel Kenny
CEO & MD

- Joined in January 2015
- Proven biopharmaceutical business leader with experience in Australia, EMEA and the US leading multiple \$1bn+ franchises



Karl Pechmann
CFO

- Accredited Chartered Accountant and Chartered Secretary
- Former CFO of listed regulatory technology company Kyckr Limited and has held several finance roles for listed and multinational corporations



David James
Global Head, Manufacturing Ops

- Pharmaceutical manufacturing operations executive with 25+ years experience



Nicole Wilson
VP, Regulatory & QA

- 10+ years Regulatory Medical Device experience
- Focused on quality compliance and marketing across Asia, South America and the Middle East



Nigel Lange
EMEA President

- 30+ years experience in the medical devices industry with a track record of success in regional and global leadership roles
- Served as Group COO and Interim Group CEO of Sirtex Medical



Charles Rowland
President, US Operations

- Strong track record of building and commercialising early stage medical device companies



Michael Warrenner
Director, Sales & Marketing

- 15+ years experience in the implantable radioactive microspheres space

Several upcoming catalysts from different commercialisation paths

News flow and catalysts

- **Announcement of the appointment of Nigel Lange** – Now
- **Humanitarian Device Exemption (HDE) filing with FDA for Bile Duct Cancer** – Q2 2020
- **Regulatory clearance in Hong Kong** – anticipated 2H20
- **Regulatory clearance in Singapore** – anticipated 2H20
- **Additional long term survival data announced** – 2H20
- **Expected first sale / procedure in UK** – 2H20
- **Expected first sale / procedure in EU** – 2H20
- **Regulatory clearance in US for Bile Duct Cancer** – anticipated Q4 2020
- **Regulatory clearance in Australia** – anticipated 2021
- **Expected first sale / procedure in US for Bile Duct Cancer** – anticipated 2021

Other announcements

- Ongoing quarterlies announcing number of new hospital centre sign ups
- Potential for partnering announcements for Pancreatic in China, Japan and other markets



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Capital Raising Details



Offer details and timetable

Capital raising of up to ~A\$19.0m via \$14.0m Placement and \$5.0m Underwritten Entitlement Offer

Event	Timing
Placement	<p>Private Placement to institutions, sophisticated and professions investors to raise up to A\$14 million via the issue of 155.1m shares:</p> <ul style="list-style-type: none"> • Issue Price A\$0.09 per share • Placement under the company's existing 25% Placement capacity under ASX Listing Rule 7.1
Entitlement Offer	<ul style="list-style-type: none"> • 1 of 11 Underwritten Non-Renounceable Entitlement Offer to existing shareholders to raise approximately A\$5 million • Placement shares are not eligible to participate in the rights issue
Pricing	<p>The Offer Price of A\$0.09 represents an approximate:</p> <ul style="list-style-type: none"> • 18.2% discount to the closing price on 28 April 2020 • 19.3% discount to the 5-day Volume Weighted Average Price (VWAP) up to and including 28 April 2020
Lead Manager & Underwriter	Bell Potter Securities Limited

Event	Timing
Trading halt	29th April 2020
Transaction announcement and company resumes trading	4th May 2020
Placement Settlement of new shares	7th May 2020
Placement Allotment of new shares	8th May 2020

Use of funds

- Funds primarily used to support commercialisation activities across UK / Europe and ASEAN regions

Key Category	Description	Amount (A\$m)
Support UK / EU Commercialisation	Additional sales resources to support new commercialisation activities for the OncoSil™ device in Europe and the United Kingdom	A\$7.3m
Support US Commercialisation for Bile Duct Cancer indication	Additional sales resources to support commercialisation activities for the OncoSil™ device in the United States in Bile Duct Cancer	A\$1.3m
APAC / ASEAN regulatory approvals	Obtain additional approvals in APAC and ASEAN markets for the commercialisation of the OncoSil™ device	A\$0.8m
US clinical trials for Pancreatic Cancer approvals	Commencement of clinical trials for approval of the OncoSil™ device in the United States for Pancreatic Cancer	A\$7.0m
General Working Capital and capital raising costs	Day to day working capital requirements	A\$2.6m
	Total	A\$19m



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Appendix



Corporate Summary

OncoSil Medical Limited (ASX:OSL)

- Proprietary brachytherapy (internal radiation) medical device
- Developing and commercialising its proprietary platform technology, **OncoSil™**; anticipating first revenues in Europe
- Milestone CE Marking and Breakthrough Device designation to help accelerate commercialisation strategy
- Patent protected in all major geographies

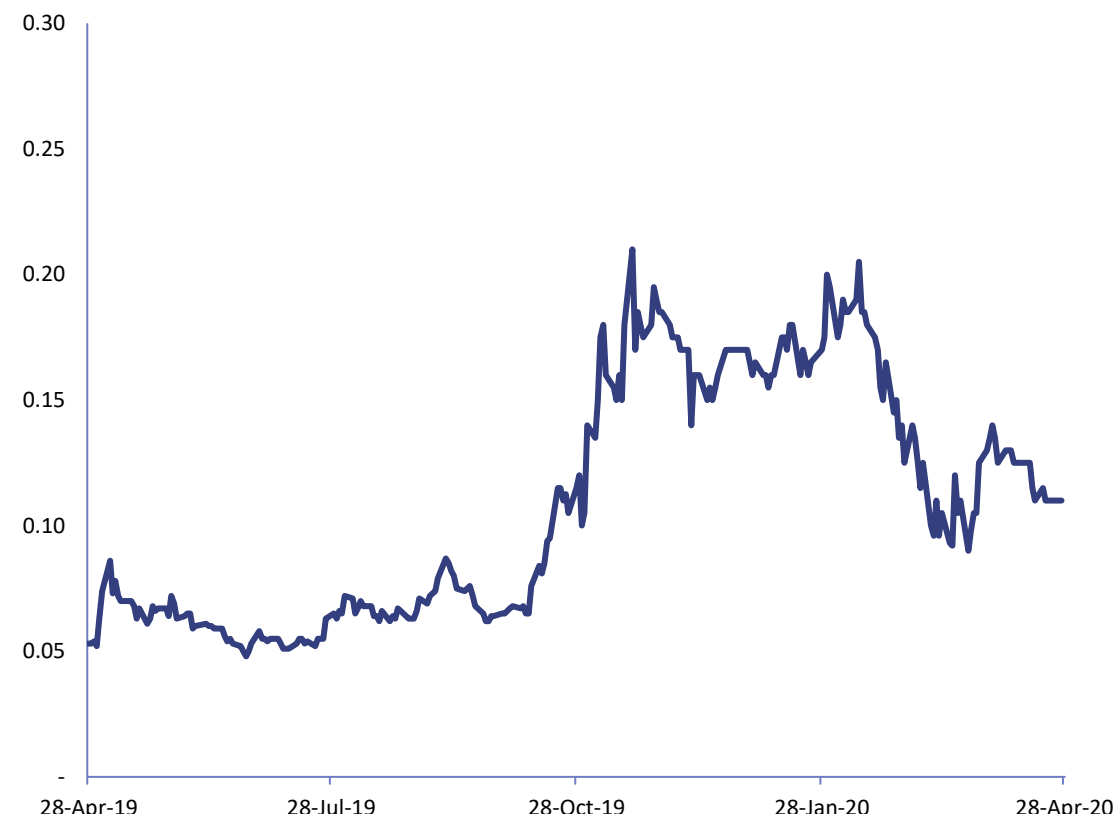
OncoSil Medical Limited (ASX:OSL)

Share price (30-Apr-20)	A\$0.11
Number of shares	620.6m
Market capitalisation	A\$68.3m
Pro-forma Cash after A\$19m raise (31-Mar-20)*	A\$23.0m
Debt (31-Mar-20)	Nil

* Not including approx. A\$2m R&D tax refund expected in Sep 20.

Share price performance (1 year)

A\$/share



A photograph of surgeons in an operating room, wearing blue scrubs, masks, and caps, illuminated by blue surgical lights. The scene is focused on the surgeons' hands and faces as they work.

1 The OncoSil™ Device

The technology provides a commercially successful treatment for hard to reach cancers

What is brachytherapy?

- Internal radiotherapy designed to treat cancer by bringing the radioactive particles physically closer to the tumour
- Historically, brachytherapy has been used to treat cervical, prostate, breast and skin cancer

Microspheres – a new form of brachytherapy

- Developed in the early 2000s, microspheres are the newest form of brachytherapy
- Significant commercial success experienced to date by leading players, Sirtex and BTG, treating liver cancer

Four key brachytherapy market segments

Market segment	Description
High-dose rate (HDR)	Radiation is delivered from implants close to, or inside, the tumour
Low-dose rate (LDR)	High dose of radiation that is delivered at a low dose rate from implants placed in the organ
Microspheres	Injected particles that permanently stay in the patient
Electronic Brachytherapy (eBT)	Technology based on the in situ generation of x-rays from a non-radioactive source

OncoSil is the first company to use brachytherapy to target pancreatic cancer, there are currently no other competitors and significant barriers to entry

Oncosil™ radiation therapy is delivered directly into the tumour



Oncosil™ is a single-use brachytherapy device to be used in conjunction with chemotherapy

Delivered through microspheres: 30-micron silicon particles contain beta-emitting Phosphorus32 (P32)

Oncosil™ microspheres are inserted directly into the cancerous tissue via endoscope

Radiation kills tumorous cells directly, with 98% of all radiation delivered within 81 days of injection

In therapeutic use 98% of the radiation is delivered within 81 days.

Oncosil™ is classified as an Active Implantable Medical Device (AIMD) and meets the requirements of a sealed source.

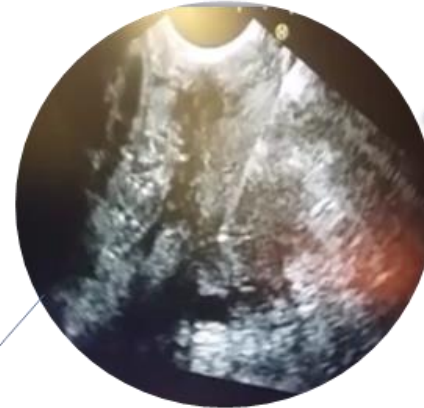
Minimally invasive procedure and allows for targeted radiation



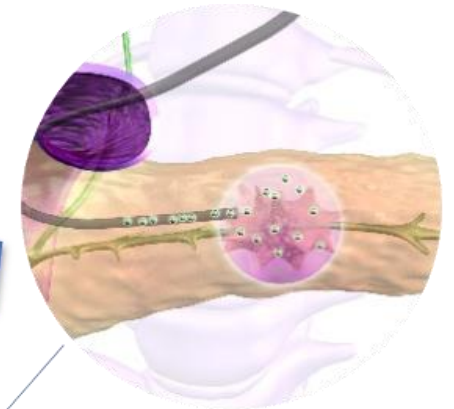
OncoSil™
Microparticles are
suspended in a
rheological Diluent



Endoscope
guided
(ultrasound) into
the upper
intestine



Using ultrasound
imaging the needle is
guided into the
target lesion

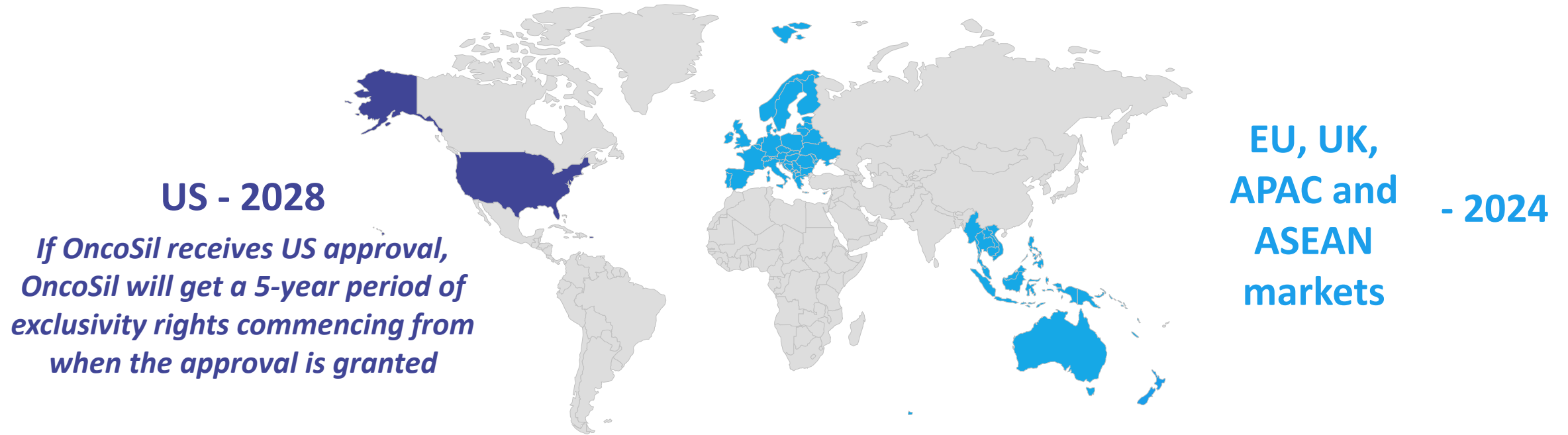


OncoSil™ injected
directly into the tumor.
Implanted Microparticle
localization shown on
Bremsstrahlung imaging

Significant patent coverage in all geographies

OncoSil is actively exploring patent extension

Existing Patent Coverage:

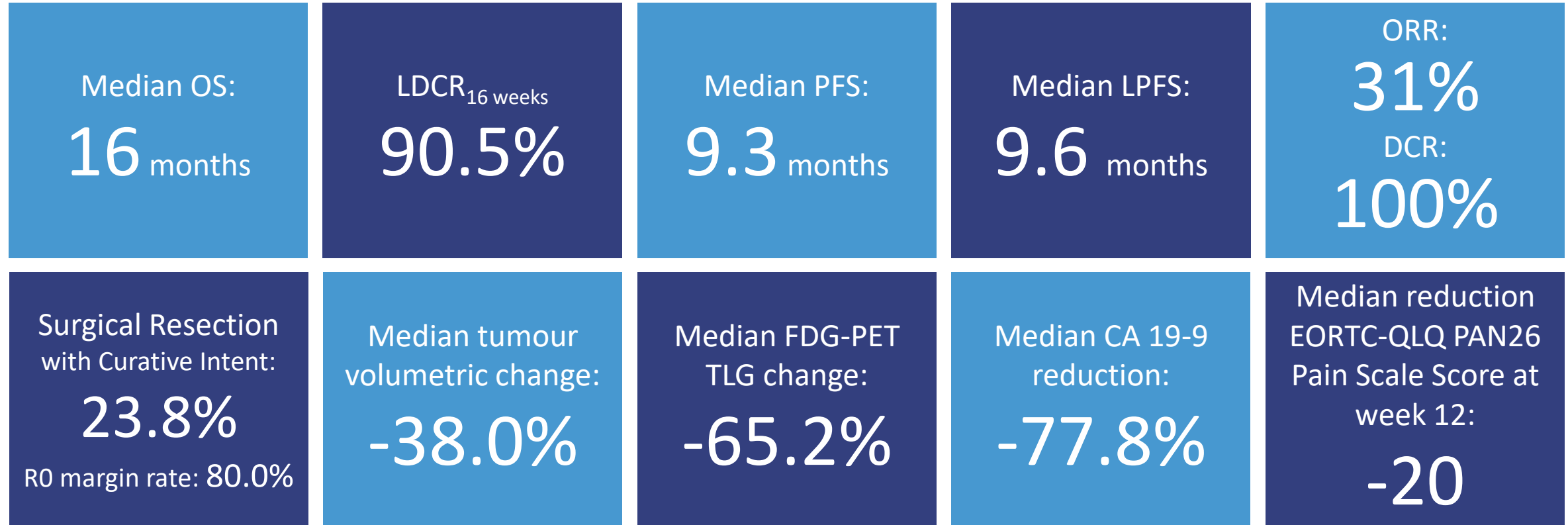


A photograph of an operating room with several large, hexagonal surgical lights hanging from the ceiling. The scene is dimly lit, with the primary light source being the surgical lamps. A blue drape is visible on the right side of the frame. The overall color palette is dominated by blues and greys.

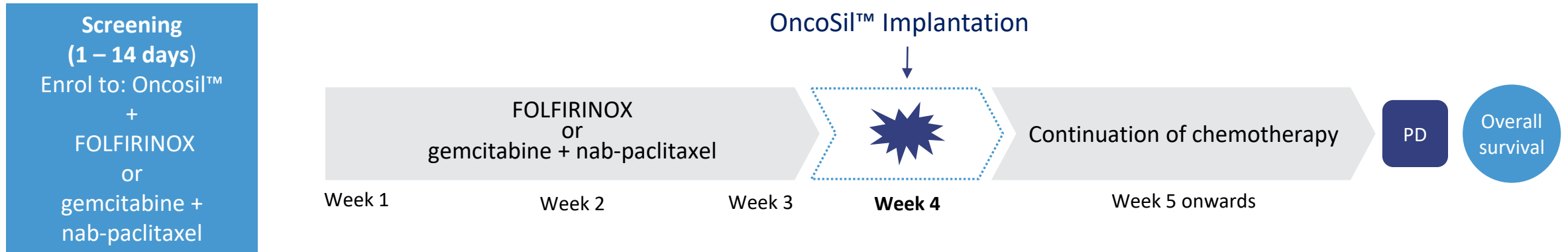
2 PanCO Trial Results

Summary of the Pan-Co results

Performance (efficacy) data for the 42 study participants implanted with the OncoSil™ device demonstrate clear benefits for patients with unresectable locally advanced pancreatic cancer



PanCO Study Design and Objective

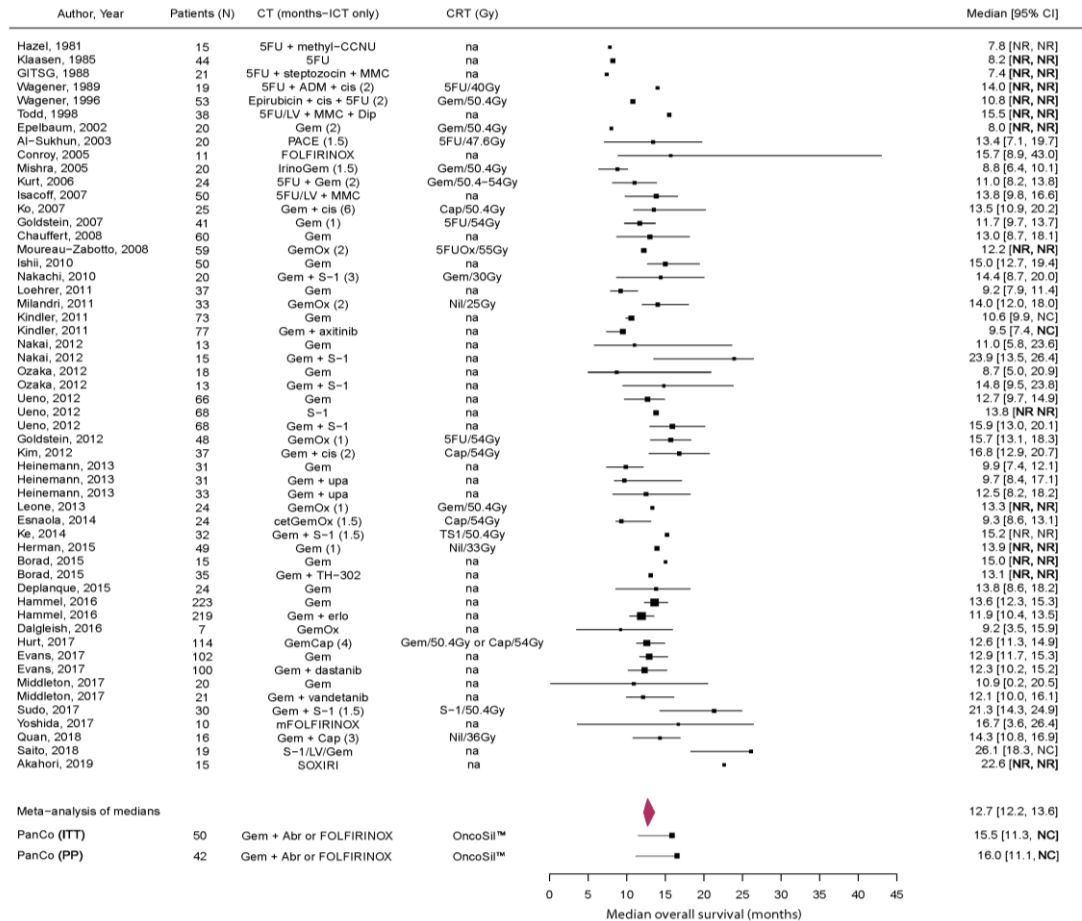


- 8 weekly CT – RECIST 1.1 and tumour volume (independent central reader analysis)
- SPECT-CT Bremsstrahlung imaging – Days 1 and 7
- Blood and urine P-32 analysis
- FDG-PET – Baseline and Week 12
- CA 19-9 tumour marker serial analysis
- Chemotherapy by physician choice

The primary objective of PanCO was to assess the **safety** of the device and determine **the feasibility of the administration** approach in the setting of advanced, unresectable pancreatic cancer, with LDCR_{16 weeks} as the primary efficacy measure

Systematic Literature Review: Overall Survival Analyses

All Identifiable Treatment Arms



Summary of Analysis

Regimen	Median OS	(95% CI)
CT-only and ICT + CCRT	12.7 months	(12.2, 13.6)
PanCO (ITT)	15.5 months	(11.3, NC)
PanCO (PP)	16.0 months	(11.1, NC)

PanCO Local Disease Control Rate at 16 weeks (LCDR_{16 weeks})

Maintenance of local tumour control: Week 24 LCDR

30/42 implanted study participants had SD, PR or had undergone surgical resection with curative intent at Week 24:

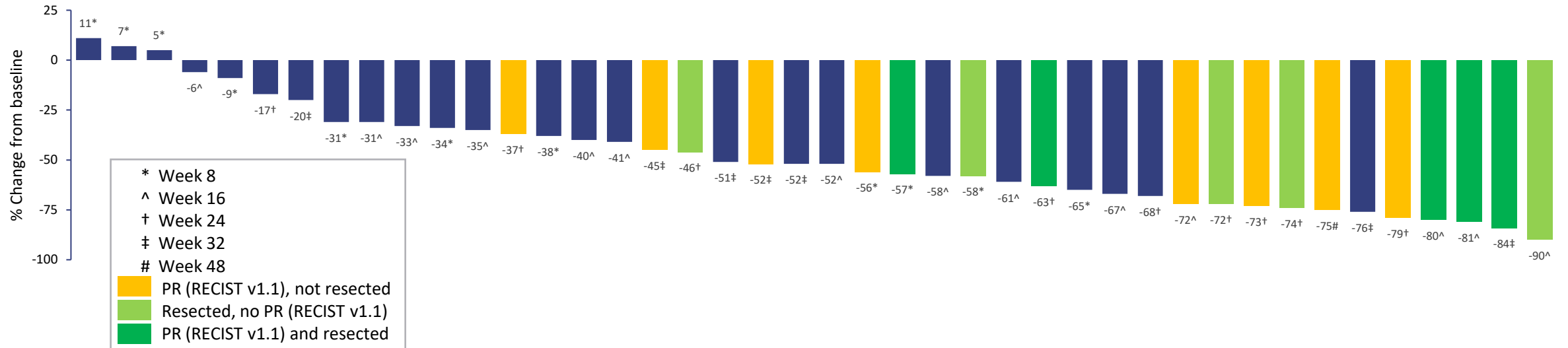
LDCR_{24 weeks} = 71.4% (95% CI: 55.4%, 84.3%)

PanCO Local Disease Control Rate at 16 weeks (LCDR_{16 weeks}) per RECIST 1.1

	ITT (N=50)	PP (N=42)
Number of study participants with local disease control at Week 16	41	38
LCDR _{16 weeks} (95% CI)	82.0% (68.6% ,91.4%)	90.5% (77.4%, 97.3%)
p-value	0.0013	<=0.0001

PanCO Tumour Volumetric Assessment

Maximum % change in tumour volume from baseline (prior to surgical resection) for each patient by outcome

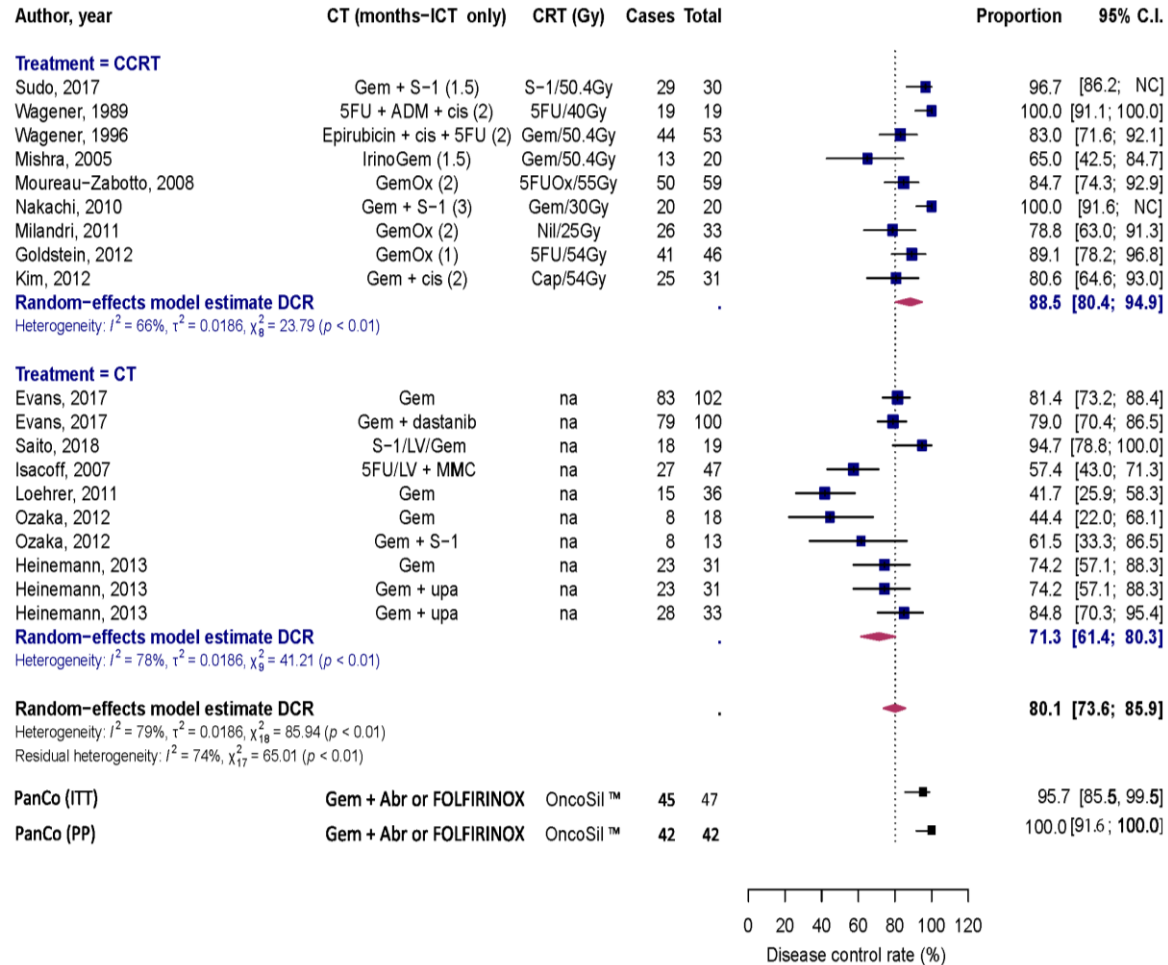


Time point	Number of patients (N*/N)	Median volumetric reduction	Mean volumetric reduction (%)	Range of volumetric change (%)	p-value
Week 16	41*/42 implanted [PP]	38.0%	30.8%	+89.0% to -90.0%	<0.0001

N* = number of assessments available for Week 16 timepoint; p-value for paired T-testing of change in tumour volume from baseline to week 16. Tumour volume calculated using Longest Diameter in axial dimension, Greatest Perpendicular Diameter in axial dimension and Longest Orthogonal Diameter in craniocaudal dimension.

Systematic Literature Review: Disease Control Rate

Subgroups Based on Treatment

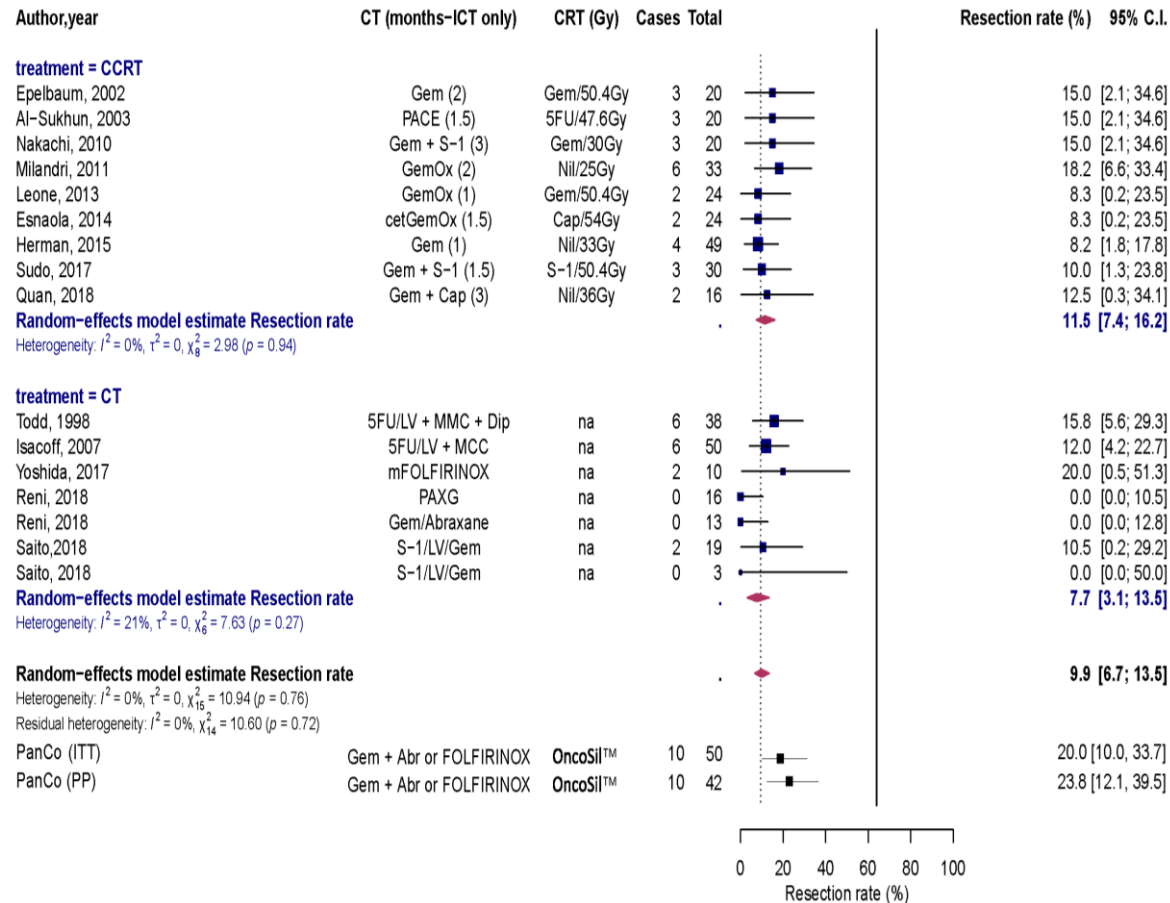


Summary of Analysis

Regimen	DCR	(95% CI)
CT-only and ICT + CCRT	80.1%	(72.9, 86.4)
CT-only	71.3%	(73.6, 85.9)
ICT + CCRT	88.5%	(80.4, 94.9)
PanCO (ITT)	95.7%	(85.5, 99.5)
PanCO (PP)	100.0%	(91.6, 100)

Systematic Literature Review: Resection Rate Analyses

Subgroups Based on Treatment



Summary of Analysis

Regimen	Resection Rate	(95% CI)
CT-only and ICT + CCRT	9.9%	(6.7, 13.5)
CT-only	7.7%	(3.1, 13.5)
ICT + CCRT	11.5%	(7.4, 16.2)
PanCO (ITT)	20.0%	(10.0, 33.7)
PanCO (PP)	23.8%	(12.1, 39.5)

Abbreviations: C.I., confidence interval; ITT, intention-to-treat (enrolled participants); PP, per protocol (enrolled and implanted participants); RR, resection rate.

Important notice

This Presentation has been prepared by OncoSil Medical Ltd (ASX:OSL) (**OncoSil** or the **Company**) to provide a general overview of the Company. This Presentation and the information contained may require further explanation and/or clarification. Accordingly, this Presentation and the information contained should be read in conjunction with past and future ASX announcements made by OncoSil and should not be relied upon as an independent source of information. Please contact OncoSil and/or refer to the Company's website www.oncosil.com.au for further information.

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The information contained in this presentation is current as at 30 April 2020.

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