



oncosil

MEDICAL
ASX.OSL

Investor Update

Advancing Pancreatic cancer treatment

Transforming the prognosis

August 2020



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

Investment Highlights



Proven world class technology: OncoSil™ is a unique and innovative platform technology with compelling clinical data for pancreatic cancer treatment - doubling of the median overall survival length and downstaging of previously unresectable patients – Platform technology can be leveraged into other indications (bile duct cancer, liver)



A clear global opportunity: >US\$3bn market opportunity to become standard of care in combination with chemotherapy; solving global unmet need for pancreatic cancer patients where surgery is not a viable option



Ready to commercialise globally: Achieved milestone CE Mark approval and Breakthrough Device designation; ready to commercialise for launch in Europe, UK and Asia



Highly attractive and scalable operating model: Strong operating leverage with high gross margins when at scale, with a low fixed cost base - low cost salesforce and a highly scalable manufacturing and distribution capability in place



Best-in-class leadership team: Highly experienced board and management team with successful track record developing, licensing and commercialising early stage drugs

In 2020, OncoSil has continued to deliver upon its stated objectives

Stated objectives from the May 2020 capital raising achieved

Appointment of Nigel Lange (ex Sirtex Europe CEO) to drive European commercialisation	
Humanitarian Device Exemption (HDE) filing with FDA for Bile Duct Cancer	
Regulatory filing in Australia	
Regulatory clearance in Singapore	
Regulatory clearance in Malaysia	
Regulatory clearance in Hong Kong (expected later this year)	

Status	 Yes	 In part	 No
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Upcoming catalysts

- **Expected first sale in UK/EU –2H CY20**
- **Regulatory decision in US for Bile Duct Cancer – anticipated 4Q CY20**
- **Regulatory clearance in Australia –anticipated 1H CY21**
- **Regulatory decision in Hong Kong – anticipated 2H CY20**

OncoSil Medical is a commercial-stage medical device company

Who are we

- Developing and commercialising its proprietary platform technology, OncoSil™
- OncoSil's first approved indication is in locally advanced pancreatic cancer
- Filed for humanitarian use indication of bile duct cancer in US

What is our technology

- Proprietary brachytherapy (internal radiation) medical device
- Implanted device (brachytherapy) delivering targeted radiation to pancreatic tumour
- Breakthrough device designation in US, Europe and parts of Australasia

What approvals have we received

- Approved to sell in UK, EU, Singapore, Malaysia and New Zealand
- Awaiting regulatory clearance in Australia and Hong Kong
- CE Mark approval
- Breakthrough designation in US, EU, UK and Singapore
- Patent protected across all key jurisdictions



What our data shows

PanCo trial results

- ✓ 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

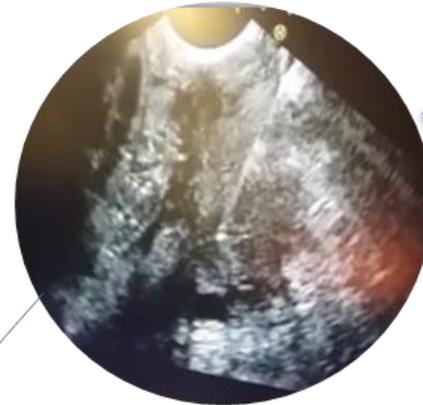
Minimally invasive procedure and allows for targeted radiation



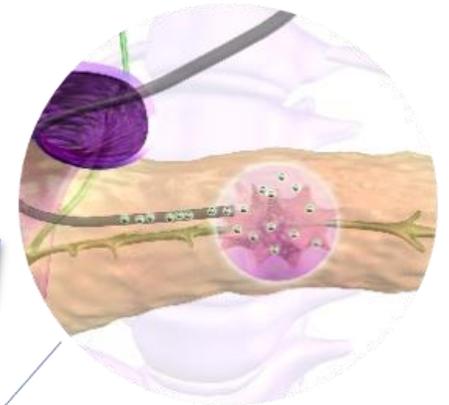
OncoSil™
Microparticles are
suspended in a
rheological Diluent



Endoscope
guided
(ultrasound) into
the upper
intestine



Using ultrasound
imaging the needle is
guided into the
target lesion

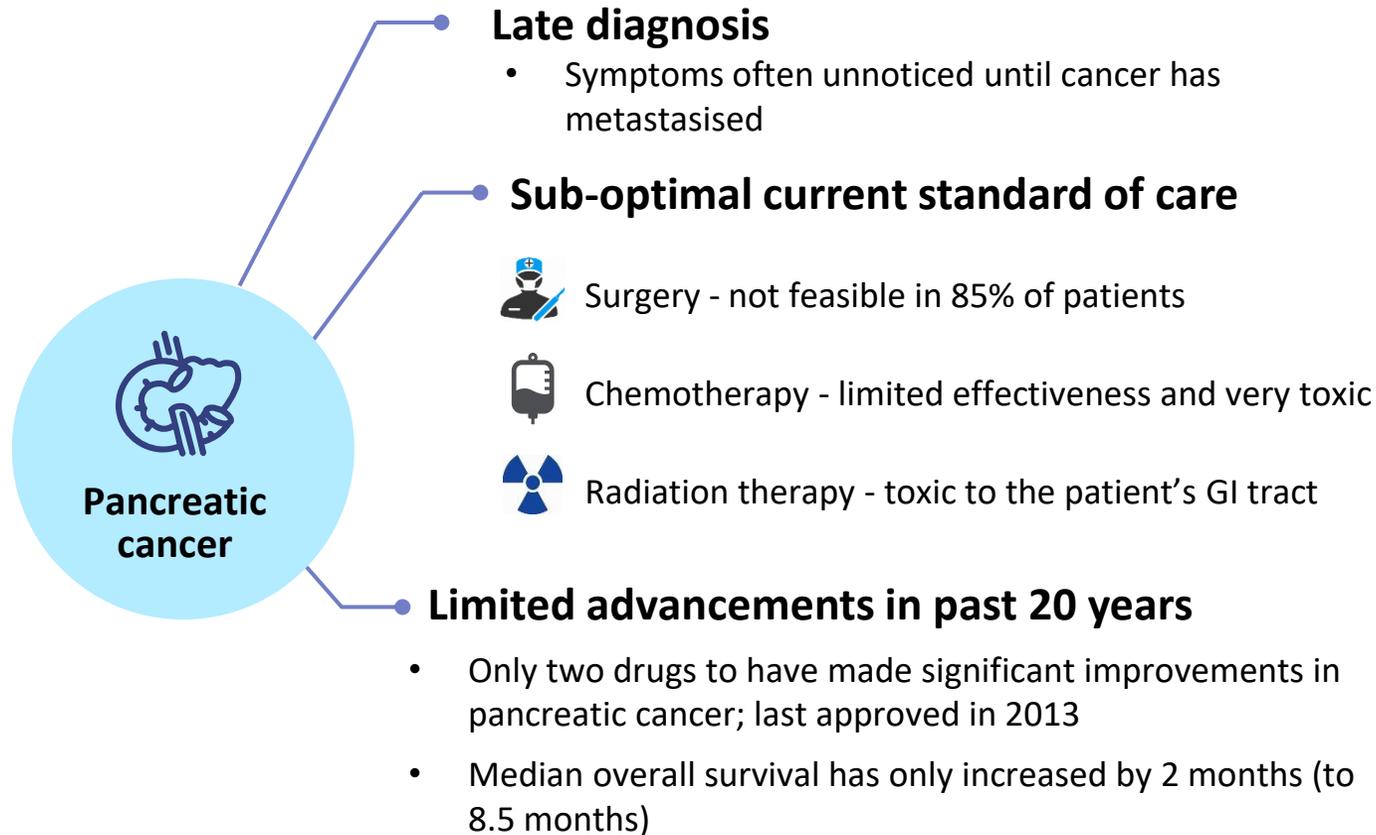


OncoSil™ injected
directly into the tumor.
Implanted Microparticle
localization shown on
Bremsstrahlung imaging

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

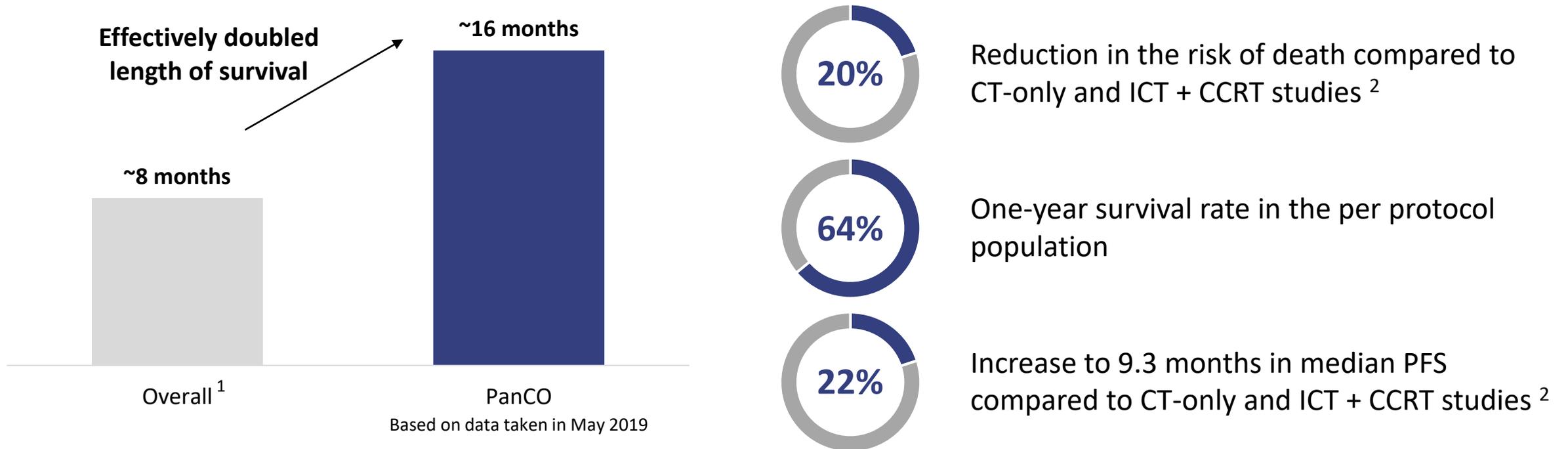
Notes.

(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

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



Survival length of ~16 months is based on data taken in May 2019, the time of the latest analysis

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

A clear market opportunity for OncoSil to become standard of care

There are more than 40k locally advanced pancreatic cancer (LAPC) cases p.a. in EU & UK ^{1,2}

	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)

(2) Based on LAPC cases equating to 40% of all pancreatic cancer cases

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	35,452	~\$890m
Singapore	Approved to sell	855	342	~\$9m
Malaysia	Approved to sell	976	390	~\$10m
Hong Kong ⁴	Approval pending	766	306	~\$8m
ANZ	Australia – Approval pending NZ – Approved to sell	4,298	1,719	~\$40m
China	Developing regulatory pathway to approval, designing trials Commercialisation via strategic partnerships	116,291	46,516	~\$1,160m
Japan	Commercialisation via strategic partnerships	43,119	17,248	~\$430m
United States	Breakthrough designation received, designing trials Targeting approval 2022/2023	50,846	20,338	~\$500m

LAPC target market size >US\$3bn p.a

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

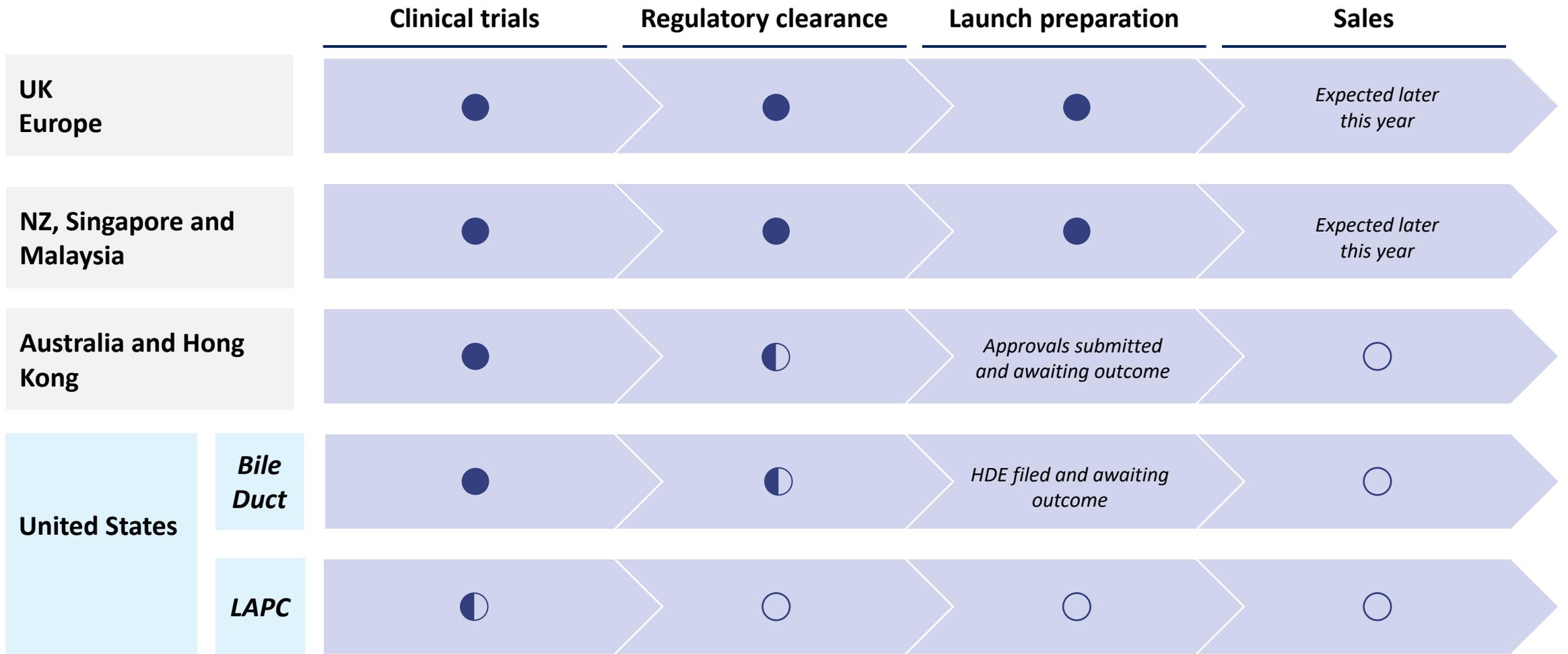
(4) Hong Kong Cancer Registry, Hospital Authority 2017. Accessed from <https://www3.ha.org.hk/cancereg/allagesresult.asp>

OncoSil's commercialisation strategy currently in full swing

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



OncoSil well progressed across key markets



Europe – clear path to first revenues

Step by step plan to achieving first revenues

Clinical trials and evidence development

- ✓ Conducted lengthy and complex PanCO clinical trial
- ✓ Compelling results and safety data from trial underpinned CE Mark
- ✓ Increased awareness and buy-in through results, ongoing publications and support of key opinion leaders

Manufacturing and supply chain

- ✓ End-to-end manufacturing capabilities, supply chain and logistics in place and validated
- ✓ Capabilities highly scalable to meet commercial launch quantities

Regulatory approvals

- ✓ Obtained Breakthrough device designation
- ✓ Obtained CE Mark in April 2020

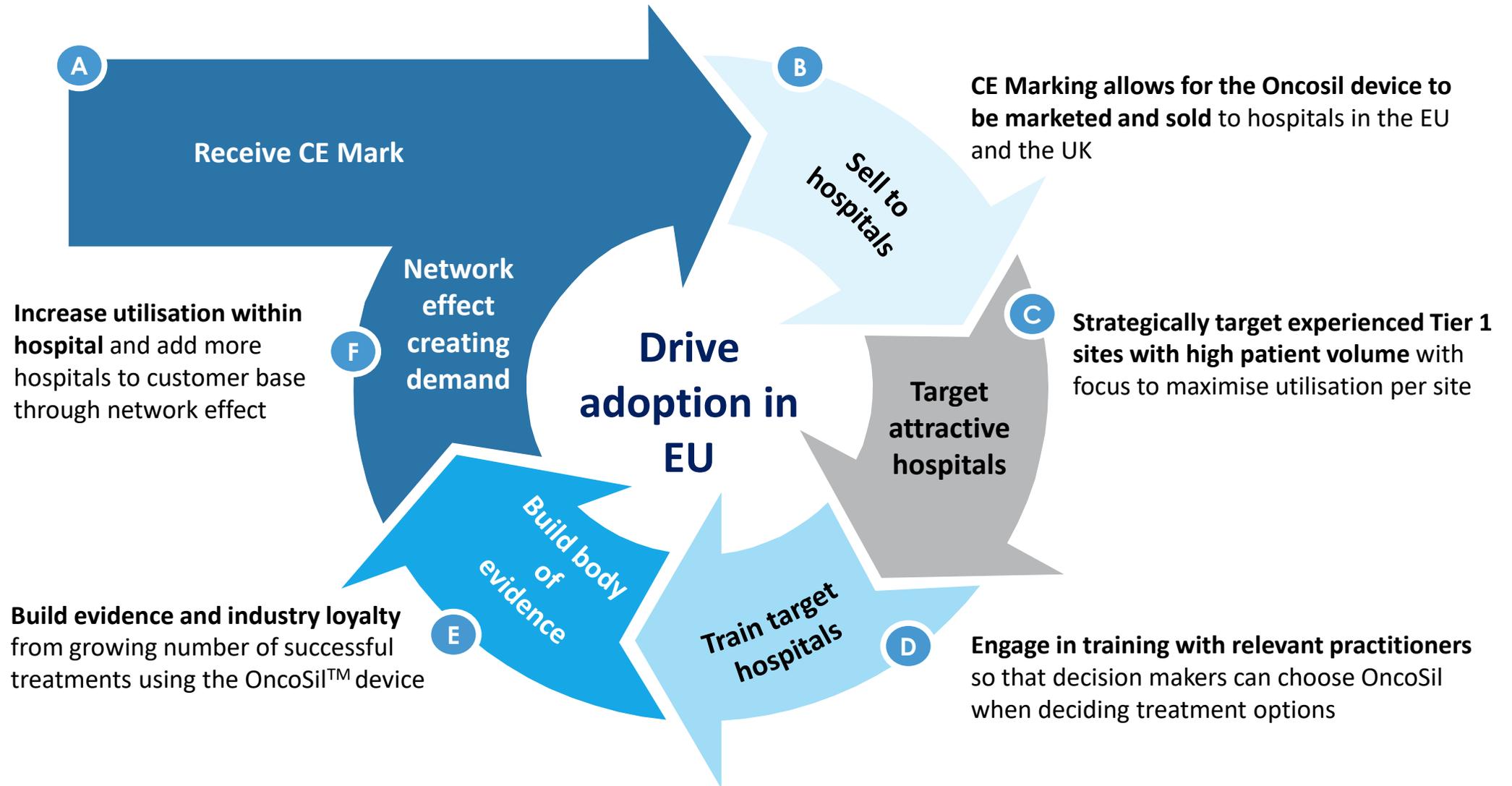
First Revenues¹

- ✓ **Appointment of Nigel Lange, ex Sirtex Europe CEO, to drive European commercialisation strategy**
- ✓ **Focus is on winning and activating large key hospitals with a small and focused sales team**
- ✓ **Customer onboarding progressing strongly for top tier hospitals**
- ✓ **First revenues expected this year**
- ✓ **We expect strong network effect and strong 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



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US – Expanding into new indications driving greater economies of scale

Bile duct pathway into US market reinforces OncoSil™ platform technology



	Bile Duct Cancer	Pancreatic cancer
Market opportunity	US\$80mn p.a ¹	US\$500mn p.a ^{2,3}
Route to US entry thus far	<ul style="list-style-type: none"> ✓ December 2018: Humanitarian Use Designation (HUD) granted by FDA ✓ July 2019: Successfully agreed with FDA that PanCO data could be used as predicate for dCCA 	<ul style="list-style-type: none"> ✓ August 2016: Investigational Device Exemption (IDE) granted by FDA ✓ March 2020: Breakthrough Device designation granted by FDA, successfully meeting its strict criteria
Forward plan	<ul style="list-style-type: none"> ✓ July 2020: HDE filing submitted Outcome expected in 4Q 2020 	<ul style="list-style-type: none"> □ Now: Working closely with FDA to optimise the Pre-market approval (PMA) evidence development and clinical trials
	Expansion into new indications	Continues to be a core focus

Notes.

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

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

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

US – Bile duct cancer market a critical part of OncoSil's US strategy



Decision to explore various US regulatory pathways

In October 2019, OncoSil announced its intention to explore additional US regulatory pathways outside of LAPC, forming OncoSil's dual entry pathway into US



HDE application submitted to FDA in July 2020

OncoSil recently submitted the Humanitarian Device Exemption (HDE) application to the FDA for the treatment of bile duct cancer



Commercialisation of bile duct cancer treatment

If successful, OncoSil will be able to sell its device in the US for the treatment of bile duct cancer, which has a market size of US\$80m p.a.¹.

Notes.

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

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 (26-Aug-20)	A\$0.11
Number of shares	829m
Market capitalisation	A\$91.2m
Net cash (30-Jun-20)	A\$21.0m
Enterprise value	A\$70.2m

Share price performance (1 year)



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

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