



# Managing Director's Presentation

Annual General Meeting  
25 November 2021

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Dr Colin Biggin

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# Clarity's clinical development pipeline

Clarity's products are progressing through Phase I and Phase II clinical trials with two open IND applications that received clearance to proceed to clinical trials from the FDA, two RPDDs and two ODDs from the FDA

Indication	Product		Discovery	Preclinical	Phase I	Phase 2	Phase 3
Prostate Cancer	SAR-bisPSMA	Theranostic					
	SAR-bisPSMA	Diagnostic					
	SAR-BBN	Diagnostic					
	SAR-BBN	Theranostic					
Neuroblastoma	SARTATE	Theranostic					
	SARTATE	Diagnostic					
NETs	SARTATE	Diagnostic					
Pan cancer (GRPr positive tumours)	SAR-BBN	Diagnostic	 				
SAR Discovery Platform	Undisclosed	Undisclosed	 				
	Undisclosed	Undisclosed	 				

Current progress

## Robust clinical trial strategy

- Developing products for both rare and large indications with high unmet needs
- Focus on high quality clinical sites and experienced investigators
- Positioning products to maximise opportunity in current treatment paradigms
- Targeting the lucrative US market for first product approvals

\*Note clinical development pipeline is indicative only, subject to review.

\*\*All US studies are conducted under IND

# US prostate cancer in numbers

**2<sup>nd</sup>**

most common cancer in  
US men

**>3.1M**

living with prostate cancer  
today in US

**1:8**

US men will develop  
prostate cancer in  
their lifetime

**34,130**

men will die annually of  
prostate cancer in the US

**248,530**

new cases of  
prostate cancer in  
the US in 2021<sup>1</sup>

**>200,000**

Patients in the US  
diagnosed with  
localised/regional  
disease annually<sup>2</sup>

**~45,000**

Patients in the US  
diagnosed annually  
with mCRPC

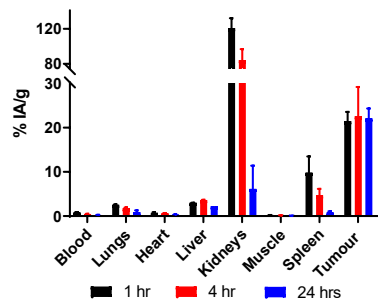
Currently investigated in our  
diagnostic strategy in prostate cancer

Currently investigated in our  
theranostic strategy in mCRPC

# SAR-bisPSMA: Pre-clinical data

SAR-bisPSMA has ideal product characteristics for a radiopharmaceutical

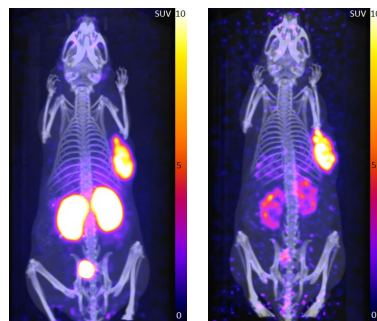
## High uptake and retention in tumour



Preclinical biodistribution study demonstrating high uptake and retention of <sup>64</sup>Cu SAR-bisPSMA in tumours with rapid clearance from non-target organs

Zia et al., 2019. Ang.Chem

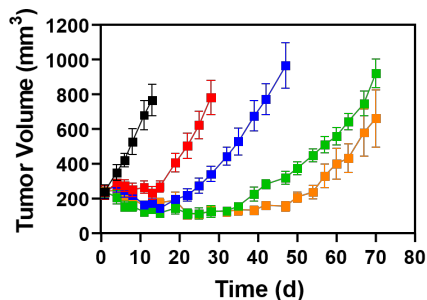
## Rapid kidney clearance of non-bound activity



1 hr 24 hr  
Tumour targeting and superior retention over 24 hours

PET images showing <sup>64</sup>Cu SAR-bisPSMA targeting to tumours over time and rapid kidney clearance

## Significant anti-tumour effect



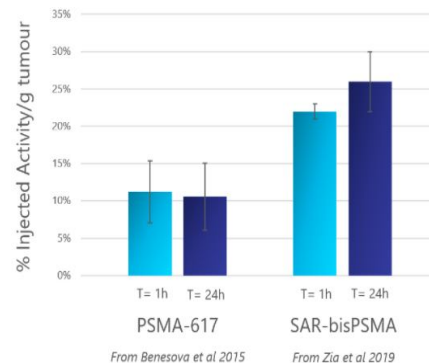
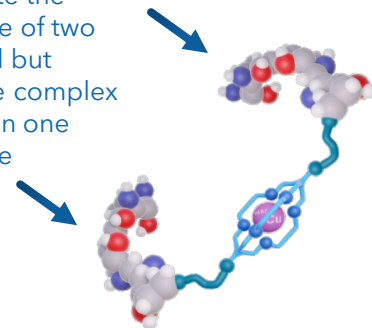
Preclinical efficacy study with increasing activity of <sup>67</sup>Cu SAR-bisPSMA (colours) demonstrating dose response

McInnes et al., 2020. JNM

■ Vehicle ■ 7.5 MBq <sup>67</sup>Cu-SARbisPSMA ■ 15 MBq <sup>67</sup>Cu-SARbisPSMA ■ 30 MBq <sup>67</sup>Cu-SARbisPSMA ■ 15 (1) + 15 (15) MBq <sup>67</sup>Cu-SARbisPSMA

## 'Bis-PSMA'

The term Bis is used to denote the presence of two identical but separate complex groups in one molecule



From Benesova et al 2015

From Zia et al 2019

# SAR-bisPSMA: Current clinical trials

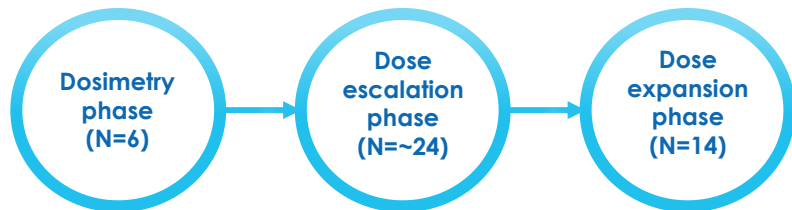
## SECURE

### SECURE: Systemic Copper theranostics in prostate cancer ([NCT04868604](#))

A Phase I/IIa study of  $^{64}\text{Cu}$  SAR-bisPSMA and  $^{67}\text{Cu}$  SAR-bisPSMA for identification and treatment of PSMA-expressing metastatic castrate resistant prostate cancer (mCRPC)

- Theranostic multi-centre, single arm, dose escalation study with a cohort expansion planned for up to 44 patients
- Recruiting in the US under an open IND
- The trial employs diagnostic PET imaging with  $^{64}\text{Cu}$  SAR-bisPSMA for selection of patients suitable for therapy cycles with  $^{67}\text{Cu}$  SAR-bisPSMA

#### SECURE study design



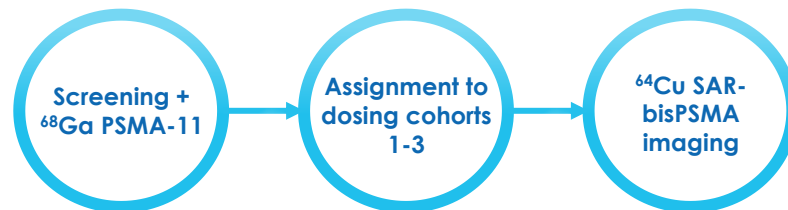
## PROPELLER

### PROPELLER: PET Imaging of Participants With Confirmed Prostate Cancer ([NCT04839367](#))

A Phase I multi-centre, blinded review, dose ranging, non-randomised study in 30 patients across Australia

- Recruiting in **early phase prostate cancer** in participants with untreated, confirmed prostate cancer and planned for radical prostatectomy
- Compare  $^{64}\text{Cu}$  SAR-bisPSMA to  $^{68}\text{Ga}$  PSMA-11, the Standard of Care for prostate cancer imaging in Australia

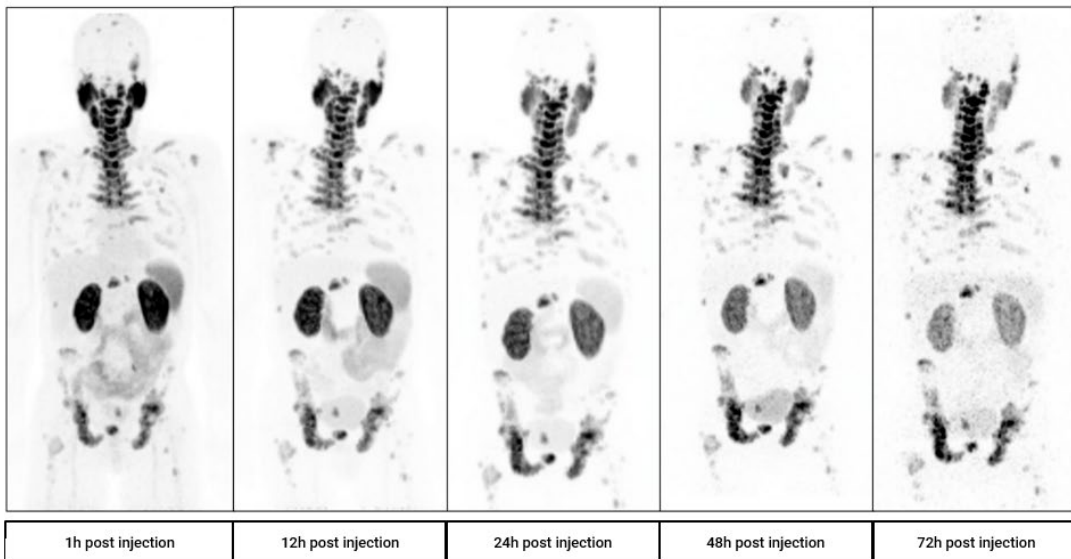
#### PROPELLER study design



# SAR-bisPSMA mCRPC therapy

Preliminary imaging results from the dosimetry phase of the theranostic SECuRE clinical trial

**PET scans in a patient with metastatic castrate-resistant prostate cancer imaged over multiple timepoints between 1 and 72 hours post administration of  $^{64}\text{Cu}$  SAR-bisPSMA (Normalized Voxel Intensity)**

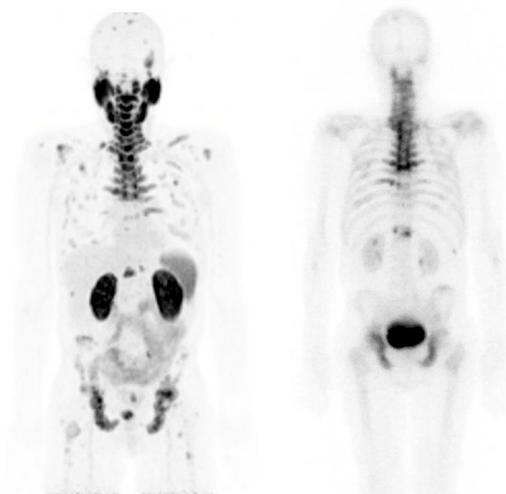


**$^{64}\text{Cu}$  SAR-bisPSMA PET/CT**



12hr  $^{64}\text{Cu}$  SAR-bisPSMA PET/CT Fused Sagittal

**Comparison of 1h  $^{64}\text{Cu}$  SAR-bisPSMA PET with  $^{99\text{m}}\text{Tc}$ -MDP Bone Scan**



1h  $^{64}\text{Cu}$  SAR-bisPSMA PET

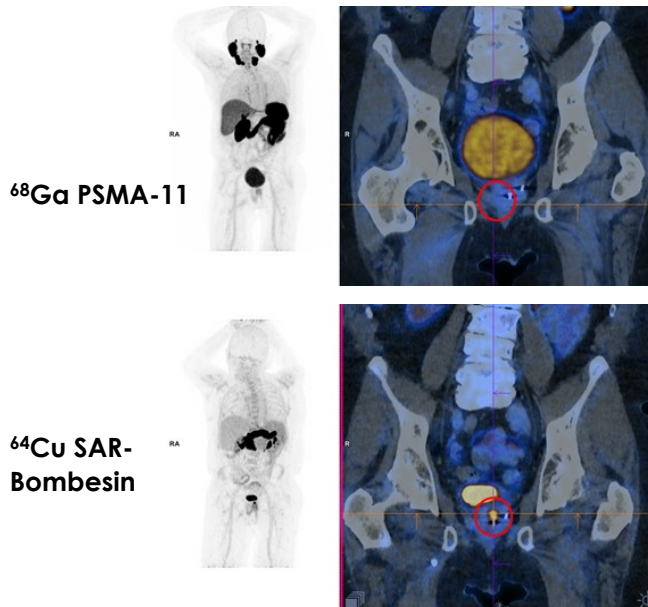
$^{99\text{m}}\text{Tc}$ -MDP WB Bone Scan

# SAR-Bombesin in prostate cancer

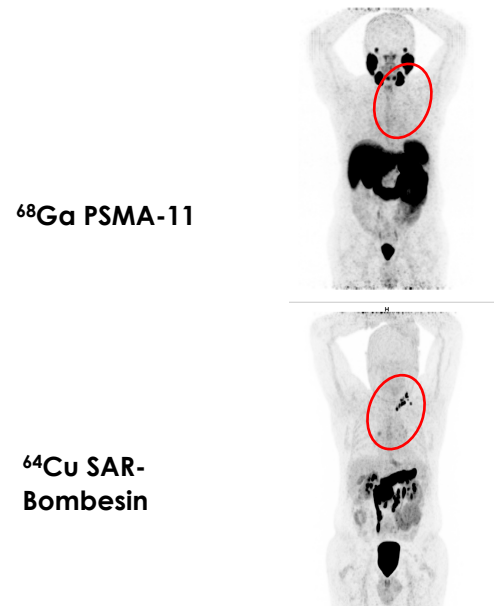
## Detection of PSMA-negative prostate cancer (PC)

- ~10% of prostate cancer patients do not **express PSMA**
- PSMA negative prostate cancer patients will not respond to PSMA imaging or therapy
- **75-100%** of prostate cancer patients **express GRPr**
- Diagnosis and treatment of these patients with TCTs targeting GRPr opens new possibilities
- Significant clinical synergies with existing SAR-bisPSMA program for clinical and development and regulatory affairs
- On-track to commence a **US diagnostic study in 2022** under an IND

$^{68}\text{Ga}$  PSMA-11 (top) images of a PSMA-negative patient with clinical signs of PC (a rising PSA score of 0.16 ng/mL) and  $^{64}\text{Cu}$  SAR-Bombesin PET/CT images of the same patient (bottom)



$^{68}\text{Ga}$  PSMA-11 (top) images of a PSMA-negative patient with history of PC (a rising PSA score of 25 ng/mL) and  $^{64}\text{Cu}$  SAR-Bombesin PET/CT images of the same patient (bottom)





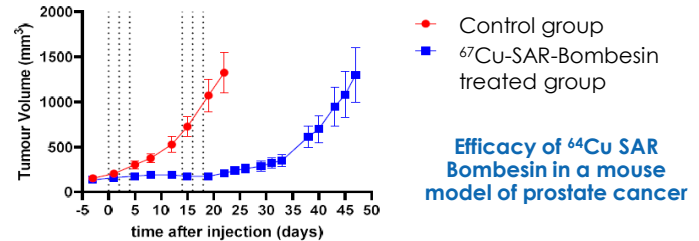
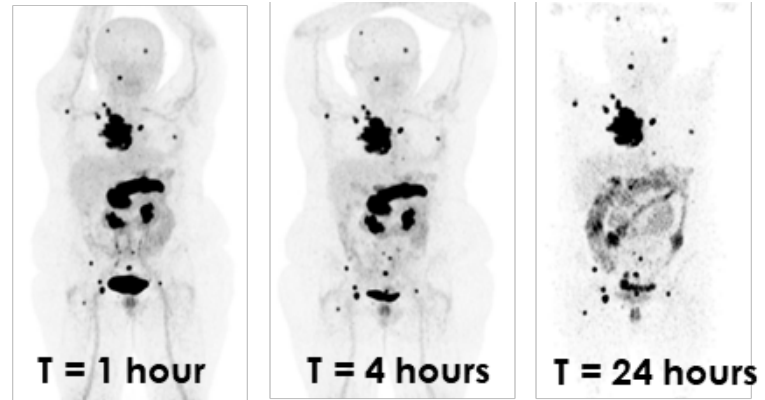
# SAR-Bombesin: A pan-cancer target

SAR-Bombesin is a highly targeted pan-cancer theranostic radiopharmaceutical being developed for identifying and selecting patients for subsequent treatment of their cancers that express gastrin releasing peptide receptor (GRPr)

## SAR-Bombesin

- GRPr is a receptor that is overexpressed in a number of cancers including prostate, breast, colon, gastric, glioma, pancreatic, small cell lung and non-small cell lung cancer, as well as renal cell cancer
- 75%-100% of prostate cancers express GRPr
- 83% of estrogen receptor (ER) positive breast cancers express GRPr
- $^{64}\text{Cu}/^{67}\text{Cu}$  SAR-Bombesin is under investigation as a theranostic pairing to treat breast and prostate cancer patients with tumours that express GRPr

### $^{64}\text{Cu}$ SAR-Bombesin in hormone positive metastatic breast cancer



$^{67}\text{Cu}$  SAR-Bombesin has demonstrated an anti-tumour effect in preclinical models of prostate cancer, when compared to the control group

# SAR-Bombesin in metastatic breast cancer

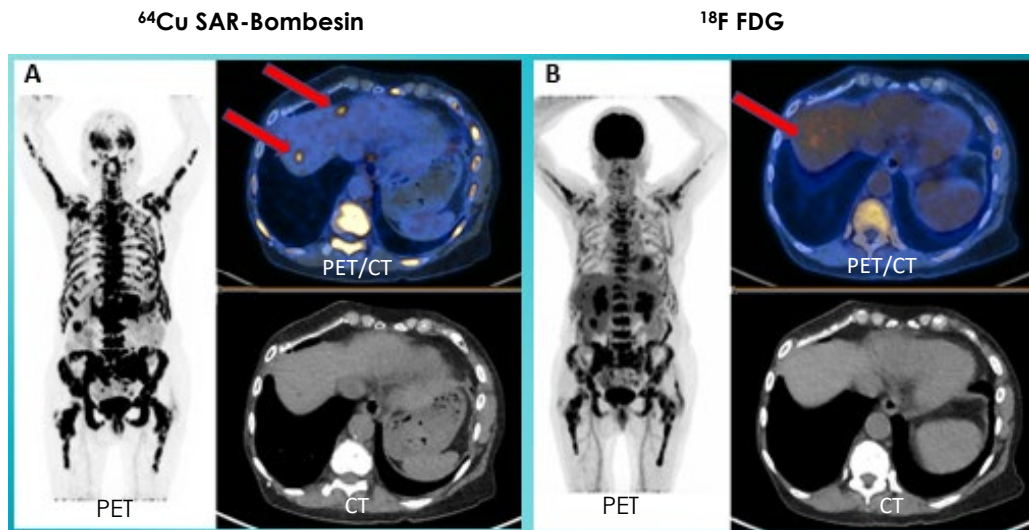
## C-BOBCAT: Recruitment closed

First-in-human pilot trial assessment of the diagnostic value of  $^{64}\text{Cu}$  SAR-Bombesin PET/CT imaging for staging of hormone positive breast cancer patients with metastatic disease in comparison with standard of care imaging (CT, bone scan and  $^{18}\text{F}$  FDG PET/CT)

- Study Sponsor: St Vincent's Hospital, Sydney
- PI: Prof. Louise Emmett

- Preliminary data from the C-BOBCAT trial shows that  $^{64}\text{Cu}$  SAR-Bombesin is highly avid with a high tumour volume compared to  $^{18}\text{F}$  FDG in some patients
- Preliminary results indicate  $^{64}\text{Cu}$  SAR-Bombesin may have a role in imaging patients with hormone positive breast cancer

### C-BOBCAT: One hour post $^{64}\text{Cu}$ -SAR-Bombesin administration in a breast cancer patient



# SARTATE™ – next generation theranostic

SARTATE™ is a highly targeted theranostic radiopharmaceutical which is being developed for diagnosing, staging and subsequently treating cancers that express somatostatin receptor 2 (SSTR2)

## Target benefits

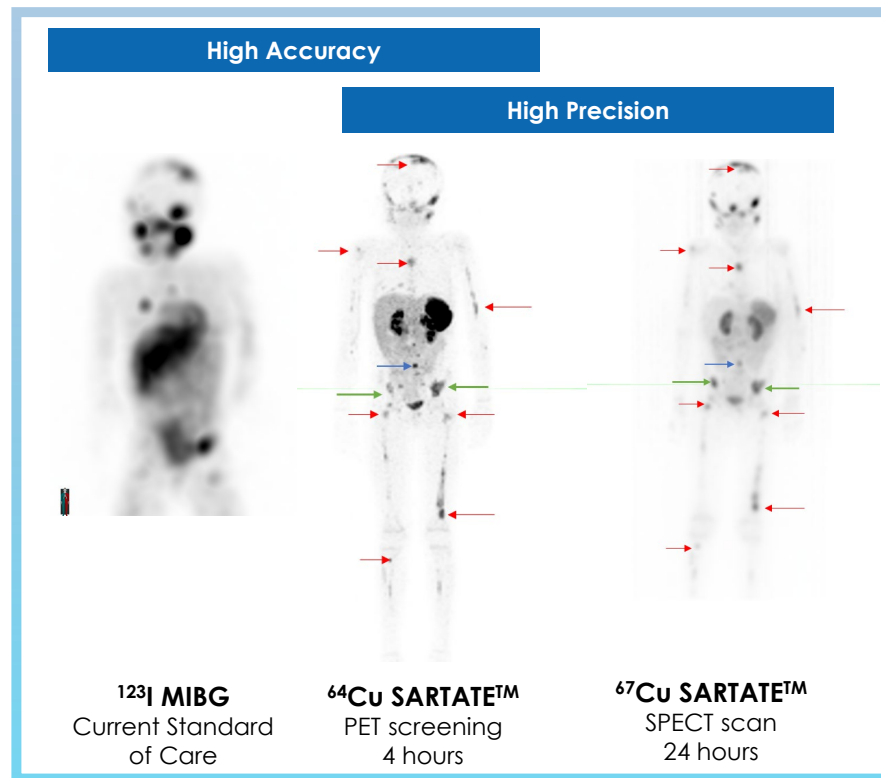
- Targets tumours that express somatostatin receptor 2 (SSTR2)
- Well characterised and substantiated peptide
- Octreotate, synthetic SSTR analogue, has been in many thousands of patients to date
- Expectation of clinical benefit (efficacy) to patients

## Current clinical development

- $^{64}\text{Cu}$  SARTATE™ for the management of neuroblastoma
- $^{67}\text{Cu}$  SARTATE™ for the treatment of neuroblastoma
- $^{64}\text{Cu}$  SARTATE™ for the management of NETs

## Future opportunities

- Other SSTR2 positive diseases, including but not limited to pancreatic and gastrointestinal cancer, pulmonary NETs, and meningiomas.



(in the same patient)

# SARTATE™: Clinical trials

## SARTATE™ CL04: <sup>67</sup>Cu-SARTATE™ Peptide Receptor Radionuclide Therapy Administered to Pediatric Patients With High-Risk, Relapsed, Refractory Neuroblastoma ([NCT 04023331](#))

- <sup>64</sup>Cu/<sup>67</sup>Cu SARTATE™ Phase I/IIa trial in high-risk neuroblastoma in the US with up to 34 patients
- Multi-centre, dose-escalation, open label, non-randomised, theranostic clinical trial.

### Neuroblastoma is one of the most aggressive childhood cancers

- 800 new cases each year in the US and the most common cancer in infants
- Neuroblastoma accounts for approximately 13% of paediatric cancer mortalities
- Approximately 84% of neuroblastomas express SSTR2





























## DISCO: Diagnostic Imaging Study of Copper-64 SARTATE using PET on patients with known or suspected NETs ([NCT 04438304](#))

- Assessing the performance of imaging agent <sup>64</sup>Cu SARTATE™ in participants with known or suspected gastroenteropancreatic NETs as a potential new way to help diagnose and manage NETs
- Phase II study recruiting in 63 patient trial at four sites in Australia with <sup>64</sup>Cu SARTATE™ manufactured centrally in Australia
- Aims to capture and highlight the significant advantages of the longer half-life (12.7 hours) of copper-64, related to imaging and product supply which are relevant to Clarity's entire pipeline of products in development
  - Comparing diagnostic performance of <sup>64</sup>Cu SARTATE™ at 4 and 20 hours to the current standard of care, <sup>68</sup>Ga DOTATATE, at one hour

# Clinical development pipeline - 12 month progress

Clarity is rapidly progressing its pipeline of TCT products through clinical development as the Company anticipates the achievement of significant milestones in the next year

Indication	Product	Therapeutic	Discovery	Preclinical	Phase I	Phase 2	Phase 3	Next Milestone
Prostate Cancer	SAR-bisPSMA	Theranostic						First therapy treatment
	SAR-bisPSMA	Diagnostic						50% recruitment in PROPELLER
	SAR-BBN	Diagnostic						Open IND for US study
	SAR-BBN	Theranostic						Open IND for US study
Neuroblastoma	SARTATE	Theranostic						Advance to cohort 2
	SARTATE	Diagnostic						Open IND for US study
NETs	SARTATE	Diagnostic						50% recruitment in DISCO
Pan cancer (GRPr positive tumours)	SAR-BBN	Diagnostic						First patient treated
SAR Discovery Platform	Undisclosed	Undisclosed						
	Undisclosed	Undisclosed						

Current progress

12 month progress

\*Note clinical development pipeline is indicative only, subject to review.

\*\*All US studies are conducted under IND

# Slide from Clarity AGM 2020

Clarity delivered on all our goals for 2021 from the last AGM

## Clarity in 2021



Five active clinical trials generating significant human trial data across all programs

- Prostate therapy data from US sites
- Prostate diagnostic data from Australia
- Neuroblastoma diagnostic and therapy data USA
- Neuroendocrine tumours diagnostic AUS
- Breast cancer data with SAR Bombesin
- Prostate cancer data with SAR Bombesin



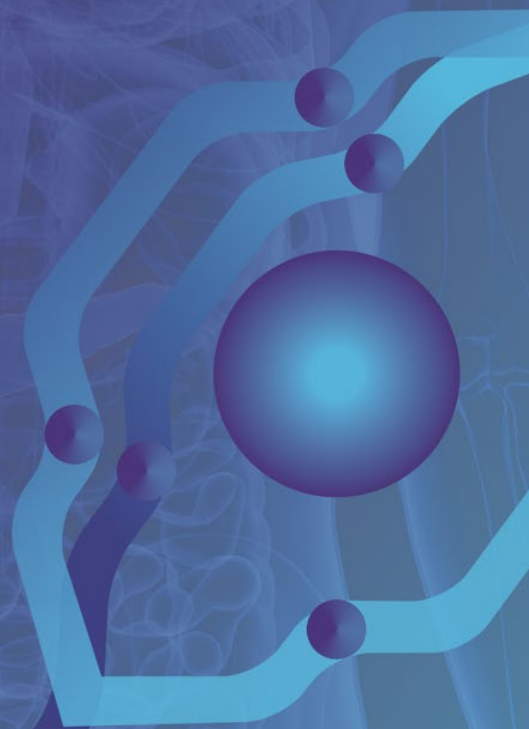
Opening INDs for 2 theranostic programs with the USA FDA (SARTATE and SAR bisPSMA)



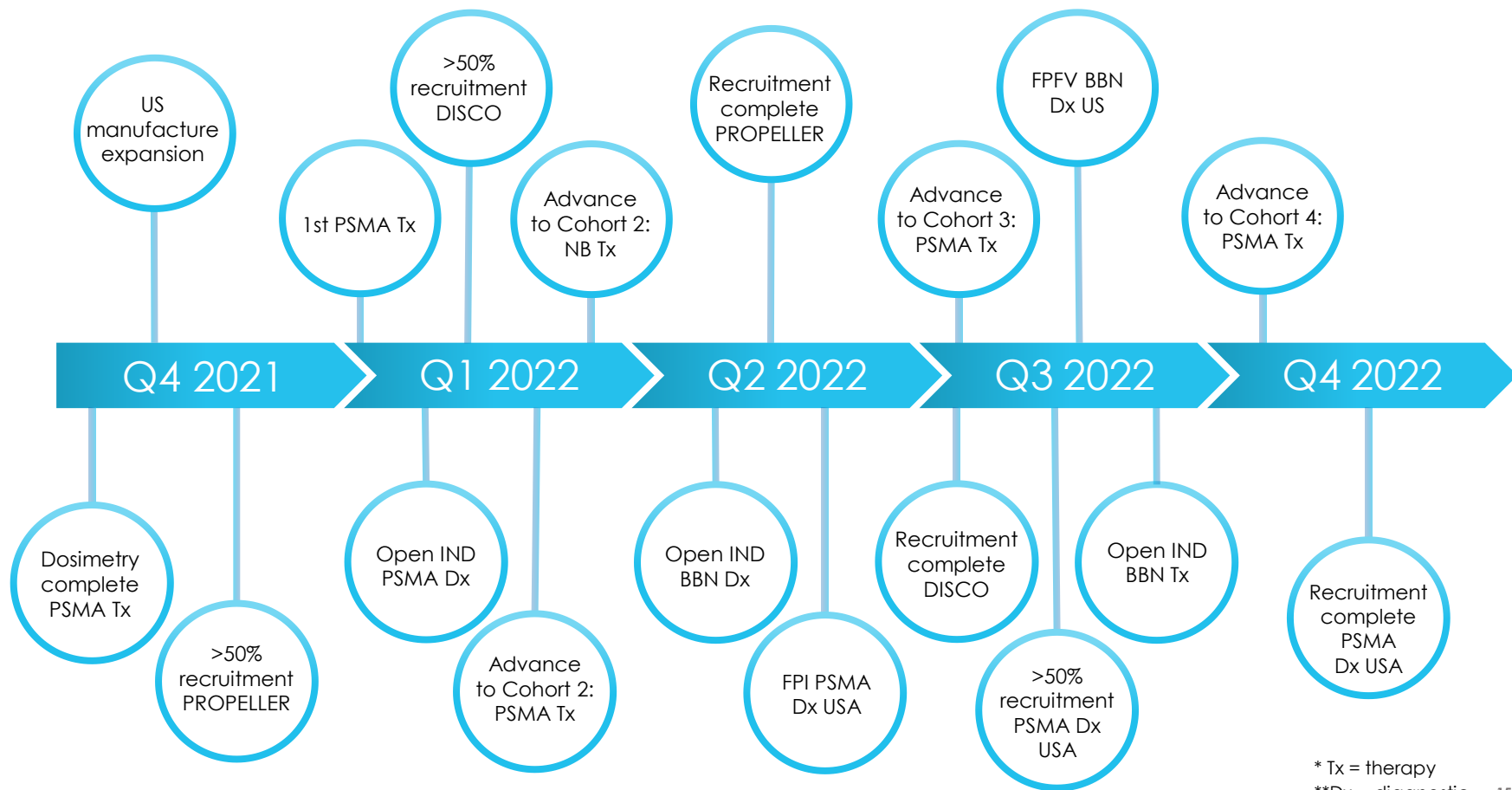
Continued strengthening of manufacturing capabilities



Development of new agents to further our pipeline



# Inflection points to Q4 2022



\* Tx = therapy

\*\*Dx = diagnostic

# Contact details

## Dr Alan Taylor

Executive Chairman

E: alan.taylor@claritypharm.com

Alan has been instrumental in the growth of Clarity over the last seven years, leading the Company from a start-up with no employees to where it is today, and heavily involved in all areas of the company. He has approximately 15 years of investment banking experience focused predominantly on the life sciences, with experience in capital raisings, mergers and acquisitions, and general corporate advisory, and has been involved in approximately \$2 billion worth of transactions.



## Dr Colin Biggin

Managing Director

E: colin.biggin@claritypharm.com

Colin has over 15 years of radiopharmaceutical development and commercialisation experience. He served with Algeta ASA from 2006-2015 during the development and commercialisation of Xofigo (radium-223) for metastatic prostate cancer and consulted to a range of biotech's and large pharma companies developing radiopharmaceuticals prior to joining Clarity in 2017.