



Bell Potter Healthcare conference

Dr Alan Taylor, Executive Chairman Dr Colin Biggin, Managing Director

10th November 2021

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Clarity business highlights

- Superior theranostic products using proprietary SAR Technology platform, achieving superior imaging and highly precise and accurate therapy
 - Multiple products in clinical development, complemented by two Investigational New Drugs (INDs) and two Rare Paediatric Disease Designations (RPDD)
 - Diverse range of assets in clinical trials which address both large indications (prostate, breast) as well as rare and orphan indications (neuroendocrine tumours, neuroblastoma)
- ELARITY
- Robust Intellectual Property (IP) position with extensive patent portfolio covering Clarity's platform, products, and pipeline
- Versatile platform technology enables discovery program focused on developing new products and new IP for a range of indications of cancer
- Growth of radiopharmaceuticals, driven by expansion of the user base who can prescribe radiopharmaceuticals and positive US reimbursement environment
- **Supply and manufacturing** of copper isotopes gives Clarity's theranostics an advantage in the commercialisation phase



Overview

Clarity Pharmaceuticals (the "Company") is a clinical stage radiopharmaceutical company developing next-generation products to address the growing need for radiopharmaceuticals in oncology

Radiopharmaceutical company with highly differentiated product portfolio

- SAR-Technology: a true platform technology that can drive out a range of radiopharmaceuticals
- Next-generation products aiming to be best-in-class
- Focused on Targeted Copper Theranostics (TCT) with copper-64 for diagnostics and copper-67 for therapy
- Significant logistical advantages and a scalable, dependable supply
- Environmental advantages over current isotopes with no reliance on nuclear fuel cycle or long-lived waste products
- High accuracy and high precision by using the chemically identical products to diagnose and treat disease
- Radio-diagnostics will be first to market, generating revenue to fund late-stage therapeutic product approvals

Targeted Copper Theranostics ("TCT")

Clarity uses a "perfect pair" of copper radioisotopes

Positron emission (PET imaging) for diagnosis

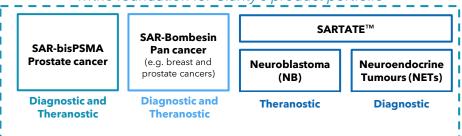
Therapeutic

67Cu SARTATE™

Beta particle (β·) emission for therapy

SAR Technology platformSuperior chelator ("cage") for copper radioisotopes

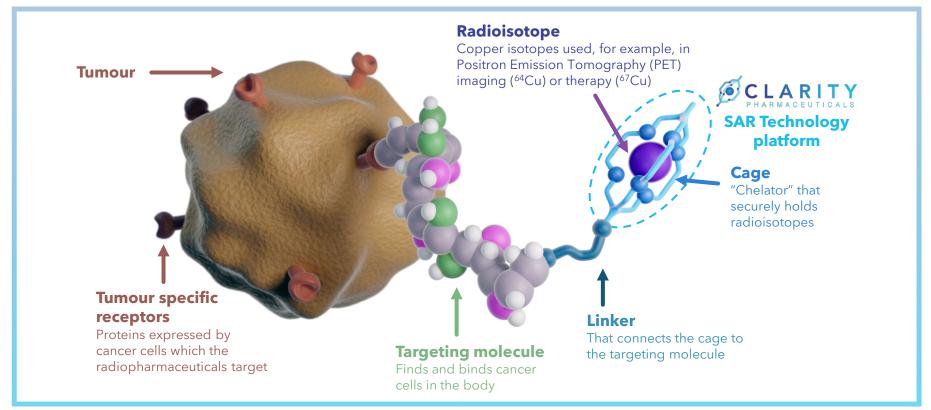
...the foundation for Clarity's product portfolio





Clarity's proprietary SAR Technology platform

Theranostic radiopharmaceuticals have four main elements: a radioisotope, cage, linker and targeting ligand and are administered intravenously





Supply and manufacturing advantages of copper

The supply and manufacturing process of copper radioisotopes gives Clarity's theranostic products an advantage in the commercialisation phase, enabling an efficient and streamlined distribution model

Copper-64 (64**Cu**)

Copper-67 (⁶⁷**Cu**)

Isotope production

- 64Cu is produced in commercial quantities on standard biomedical cyclotrons that are equipped with solid targetry¹
- ~20Ci/740GBq per ~6hr run at 180µA beam current or > 500 patient doses/run
- Multiple 64Cu supply agreements in place for both US and AUS

Logistics

- 12.7 hour half life of 64Cu facilitates central manufacture of final drug products and overnight shipment to treatment centres
- 64Cu based TCTs have a shelf life of ~48 hours (compared to ~4 h for 68Ga based products)
- Well established supply chains exist for centrally manufactured 123 I ($t_{1/2} = 13 \text{ h}$)

End users

- Product on demand in required volumes
- Flexibility for in time of administration and scanning yet fits into established patient flow at clinic
- Provides the option to re-image the patient at later time points

Isotope production

- High purity ⁶⁷Cu produced domestically in the US on electron accelerators by multiple organizations
- Up to 40Ci/1480GBq ⁶⁷Cu per day is possible² with a single high energy electron accelerator (Rhodotron), >100 patient doses/day
- NorthStar Medical Isotopes have 2 Rhodotrons being commissioned in the US and 6 more on order
- Clarity has a Supply Agreement with NorthStar, for supply of ⁶⁷Cu exclusively to Clarity

Logistics

 Overnight transport logistics of finished drug products to treatment centres are adequate for ⁶⁷Cu due to its 2.6 day half-life

End users

- Reliable product unaffected by reactor outages
- Environment friendly, non-uranium based production with no long-lived radioactive impurities



- Scalable production with abundant starting material for production (64Ni for 64Cu and 68Zn for 67Cu)
- Currently, no known competition for existing ⁶⁷Cu supply



Clinical supply of ready-to-use TCT

Development of robust manufacturing network for current and future US product supply

Growing our TCT manufacturing footprint in the USA



Washington Uni St Louis

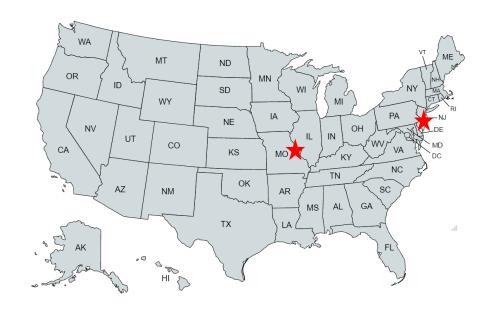




Evergreen Theranostics, NJ 🛨



- Ready-to-use copper-64 and copper-67 based products can be shipped overnight to any zip-code in the US
- Additional TCT manufacturing sites coming on board shortly
- Rolling out to additional clinical sites in 2022, which will eventually lead to full US supply from centralised manufacturing sites





Clinical supply of ready-to-use TCT

Development of robust manufacturing network for current and future US product supply

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Washington Uni St Louis

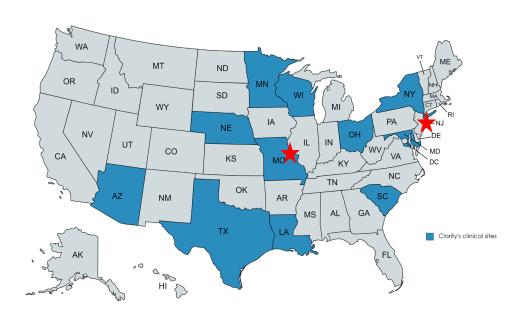




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Clinical supply to our current clinical trial sites (States shown in blue)



Clinical benefits of the copper isotope "perfect pair"

High Accuracy

Achieved by only treating those patients who show product uptake in the tumour in the diagnostic PET scan

Copper-64 based diagnostic imaging scan



Copper-67 based Therapy **Neaative** for target



Conventional **Therapy**

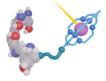
High Precision

Achieved by using the same targeting molecule with the same chemical element inside the chelator

Diagnostic

Therapeutic

64Cu SARTATE™



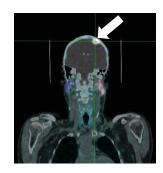
Positron emission (PET imaging) for diagnosis

Clinical Evidence



Beta particle (B-) emission for therapy

64Cu SARTATE™ PET/CT Screening



67Cu SARTATE™ 4 hour SPECT



The diagnostic and therapeutic product localise to exactly the same tumour (white arrow) in this patient with a brain tumour (meningioma)



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

Clinical development pipeline

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

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

Current progress

12 month progress

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

**All US studies are conducted under IND



US prostate cancer in numbers

1:8

US men will develop prostate cancer in their lifetime

34,130

men will die annually of prostate cancer in the US

2nd

most common cancer in US men

>3.1M

living with prostate cancer today in US

248,530

new cases of prostate cancer in the US in 2021

~45,000

Patients in the US diagnosed annually with mCRPC

Currently investigated in our theranostic strategy in mCRPC

Currently investigated in our diagnostic strategy in prostate cancer

>200,000

Patients in the US diagnosed with localised/regional disease annually²

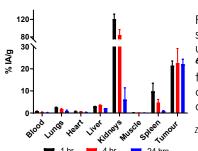
CLARITY

American Cancer Society. Cancer Facts & Figures 2021. Atlanta: American Cancer Society; 2021.

SAR-bisPSMA: Pre-clinical data

SAR-bisPSMA has ideal product characteristics for a radiopharmaceutical

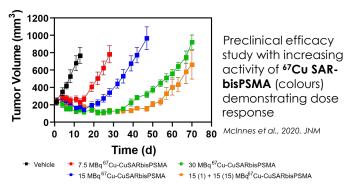
High uptake and retention in tumour



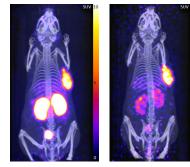
Preclinical biodistribution study demonstrating high uptake and retention of ⁶⁴Cu SAR-bisPSMA in tumours with rapid clearance from non-target organs

Zia et al., 2019. Ang.Chem

Significant anti-tumour effect



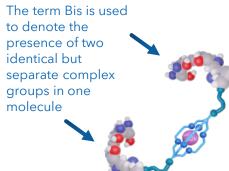
Rapid kidney clearance of non-bound activity

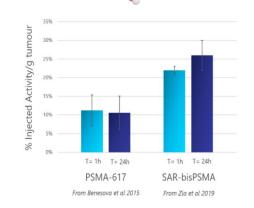


1 hr 24 hr Tumour targeting and superior retention over 24 hours

PET images showing ⁶⁴Cu SARbisPSMA targeting to tumours over time and rapid kidney clearance

'Bis-PSMA'







SAR-bisPSMA: Current clinical trials



SECURE: Systemic Copper theranostics in prostate cancer (NCT04868604)

A Phase I/IIa study of ⁶⁴Cu SAR-bisPSMA and ⁶⁷Cu 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 64Cu SARbisPSMA for selection of patients suitable for therapy cycles with 67Cu SAR-bisPSMA

SECuRE study design



PR必PELLER

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 ⁶⁴Cu SAR-bisPSMA to ⁶⁸Ga PSMA-11, the Standard of Care for prostate cancer imaging in Australia

PROPELLER study design

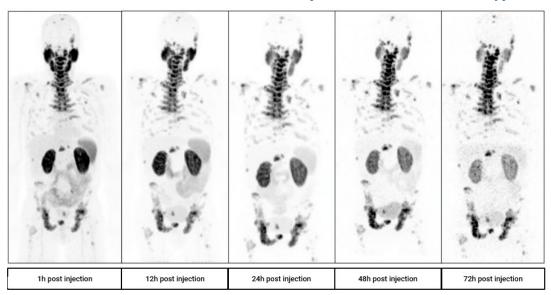




SAR-bisPSMA mCRPC therapy

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 ⁶⁴Cu SAR-bisPSMA (Normalized Voxel Intensity)

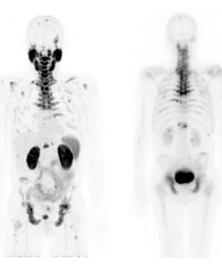


64Cu SARbisPSMA PET/CT



12hr ⁶⁴Cu SARbisPSMA PET/CT Fused Sagittal

Comparison of 1h ⁶⁴Cu SARbisPSMA PET with ^{99m}Tc-MDP Bone Scan



1h ⁶⁴Cu SARbisPSMA PET

99mTc-MDP WB Bone Scan



SAR-Bombesin in prostate cancer

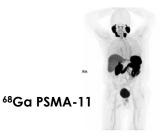
64Cu SAR-

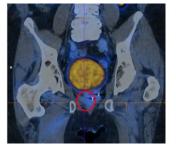
Bombesin

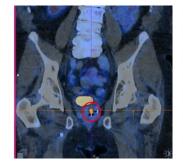
Detection of PSMA-negative prostate cancer (PC)

- ~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

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







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



⁶⁸Ga PSMA-11



64Cu SAR-Bombesin



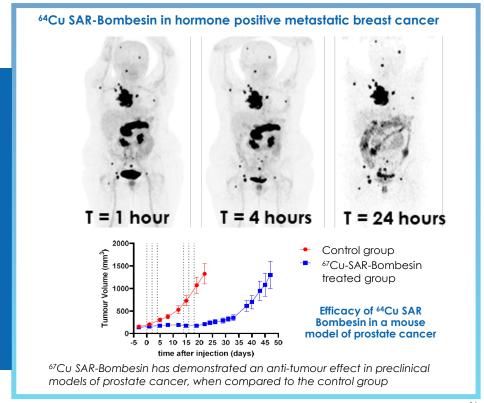
SAR-Bombesin: A pan-cancer target

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
- 64Cu/67Cu SAR-Bombesin is under investigation as a theranostic pairing to treat breast and prostate cancer patients with tumours that express GRPr



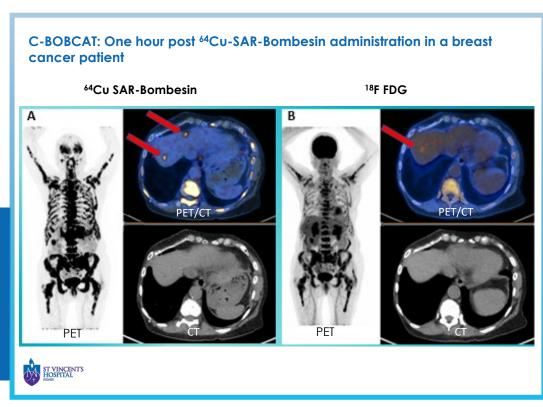


SAR-Bombesin in metastatic breast cancer

C-BOBCAT: Recruitment closed

First-in-human pilot trial assessment of the diagnostic value of ⁶⁴Cu 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 ¹⁸F FDG PET/CT)

- Study Sponsor: St Vincent's Hospital, Sydney
- PI: Prof. Louise Emmett
- Preliminary data from the C-BOBCAT trial shows that ⁶⁴Cu SAR-Bombesin is highly avid with a high tumour volume compared to
 ¹⁸F FDG in some patients
- Preliminary results indicate ⁶⁴Cu SAR-Bombesin may have a role in imaging patients with hormone positive breast cancer





SARTATETM – 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

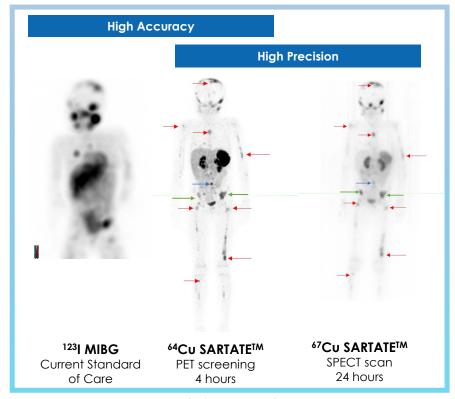
- Targets tumours that express somatostatin receptor 2 (SSTR2)
- Well characterised and substantiated peptide
- Octreotate, synthetic SSTR analogue, has been in many thousands of patients to date
- Expectation of clinical benefit (efficacy) to patients

Current clinical development

- 64Cu SARTATETM for the management of neuroblastoma
- 67Cu SARTATETM for the treatment of neuroblastoma
- 64Cu SARTATETM for the management of NETs

Future opportunities

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





SARTATETM: Clinical trials

SARTATETM CL04: ⁶⁷Cu-SARTATETM Peptide Receptor Radionuclide Therapy Administered to Pediatric Patients With High-Risk, Relapsed, Refractory Neuroblastoma (NCT 04023331)

- 64Cu/67Cu SARTATE™ Phase I/IIa trial in high-risk neuroblastoma in the US with up to 34 patients
- Multi-centre, dose-escalation, open label, nonrandomised, 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



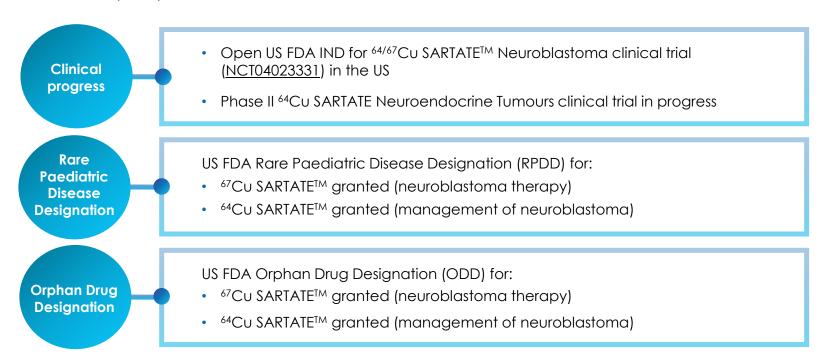
DISCO: Diagnostic Imaging Study of Copper-64 SARTATE using PET on patients with known or suspected NETs (NCT 04438304)

- Assessing the performance of imaging agent ⁶⁴Cu SARTATETM 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 ⁶⁴Cu 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 ⁶⁴Cu SARTATETM at 4 and 20 hours to the current standard of care, ⁶⁸Ga DOTATATE, at one hour



SARTATE™ regulatory milestones

Clarity has reached several regulatory milestones and approvals from the US FDA including the award of two Rare Paediatric Disease Designations (RPDD) which may <u>potentially</u> allow the company to access two Priority Review Vouchers (PRVs)

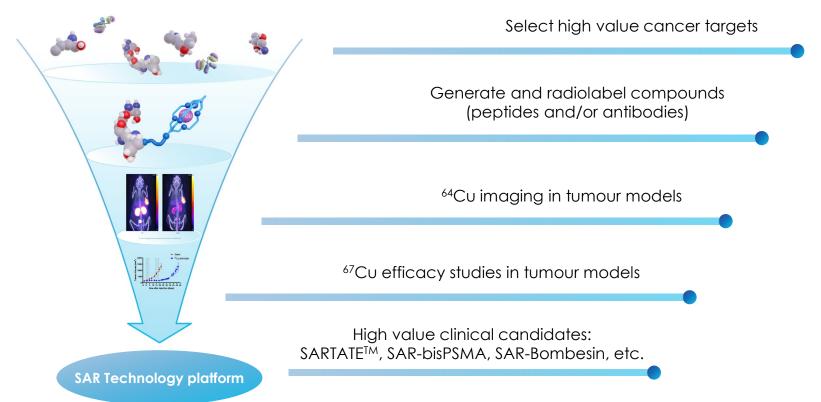


PRVs are tradeable and have recently transacted at approximately US\$100M



Clarity's Discovery Program

Clarity's SAR Technology platform can be used in conjunction with any number of targeting ligands to create new products





Robust Intellectual Property position

Clarity has a broad patent portfolio protecting its Clarity's proprietary SAR Technology platform, existing products, Discovery Program, and Manufacturing and Process protection

Broad patent protection

- Clarity has an extensive patent portfolio generated from its patent strategy to cover its platform SAR Technology, radiopharmaceutical products and pipeline of Discovery Program products
- The SAR Technology platform is covered by granted patents and new patent applications over a broad family of novel SAR (sarcophagine) cages (chelators) and linkers
- Current patent portfolio covers a broad range of countries and major markets, including United States, Australia, Europe, Japan, China, Canada, Singapore, Malaysia, South Korea, Russia, Mexico and India





Platform Protection

 Granted and new chelator patents used in further developing lead and back-up products



Product Protection

- Maintenance of pending applications for potential continuation or divisional filings (on existing important patents)
- New patents filed on lead and back-up compounds



Pipeline Protection

- New chelator patents used in future discovery products
- New patents filed on novel treatment regimes for radiopharmaceutical and imaging applications

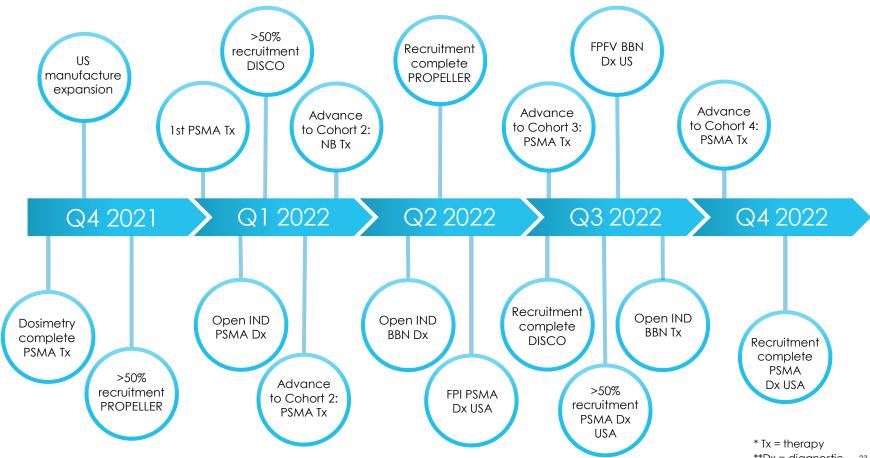


Manufacturing and process protection

- Manufacturing and formulation patents
- New patents filed on manufacturing processes



Inflection points to Q4 2022



Board of Directors

Clarity's board has extensive capital markets, radiopharmaceutical and broader life sciences experience

Dr Alan TaylorExecutive Chairman

Dr Colin BigginManaging Director

Rosanne Robinson Non-Executive Director **Dr Chris Roberts**Non-Executive Director

Dr Thomas Ramdahl Non-Executive Director **Dr Gillies O'Bryan-Tear** Non-Executive Director Mr Robert Thomas
Non-Executive Director



Dr Taylor has been instrumental in the arowth of the Company and has been heavily involved in all areas of the Company's business. Dr Taylor has approximately 15 years of investment banking experience focused predominantly on the life sciences sector, and has significant expertise in capital raisings, mergers and acquisitions, and general corporate advisory. Prior to ioining Clarity, Dr Taylor was an Executive Director of Intea Limited, a boutique Australian investment bank.



Dr Biggin has over 15 years of radiopharmaceutical development and commercialisation experience. Dr Biggin previously served with Algeta ASA during the development and commercialisation of its product Xofiao (radium-223 dichloride) for metastatic prostate cancer, which was approved by the FDA in 2013. Prior to joining the Company, Dr Bigain also consulted to a range of biotech and large pharmaceutical companies developing radiopharmaceuticals.



Ms Robinson brings extensive experience in the nuclear field and a range of commercial expertise to the Company and has over 25 years of experience in both governance and management roles in public and private companies and government. Ms Robinson is the General Manager of Business Development at Australian Nuclear Science and Technology Organisation. Ms Robinson's in-depth knowledge of the nuclear medicine industry provides the Company with a clear vision across the dynamics of, and most recent changes in, the sector.



Dr Roberts has over 40 years of experience in the medical innovation space and has served on the boards of a number of ASXlisted companies during his career. Dr Roberts was previously the CEO of ASXlisted company Cochlear Limited and Chairman of ASX-listed company Sirtex Medical Ltd. Dr Roberts was also Executive Vice-President and a director of the dual-listed (ASX and NYSE) company ResMed Inc., a global sleep disorder treatment company. Dr Roberts is Chairman of the ASX-listed company Oncosil Ltd.



Dr Ramdahl is a pharmaceutical executive with over 20 years of clinical and development experience. In 2001, he became President and the first CEO of Algeta ASA. When Dr Ramdahl joined Algeta, he was one of six employees and he played an instrumental role in its success, serving in several senior positions within the company through to and post the acquisition of Algeta by Bayer AG in 2014 for US\$2.9 billion. Dr. Ramdahl has authored more than 40 publications and is a co-inventor of several patents. Dr Ramdahl serves as Chairman of Precirix (Belgium) and AppSens AS (Norway).



Dr O'Bryan-Tear has over 30 vears of experience in the pharmaceutical industry in clinical development. medical management and commercial roles. He has held senior leadership roles in large and small pharmaceutical and biotech companies in the US and Europe and has been involved in multiple product approvals. He was previously the Chief Medical Officer of Algeta ASA. Dr O'Bryan-Tear has been an adviser to several US and European biotech companies and is a member of the Scientific Advisory Board of Fusion Pharmaceuticals Inc. (Canada).



Mr Thomas has a strona background in financial services and capital markets including advising on the IPOs of the Commonwealth Bank of Australia and Qantas. He is the former CEO of County NatWest Securities and of Citi Corporate and Investment Bank Australasia, Mr Thomas has held the position of Chairman at Australian Wealth Management Ltd, TAL. HeartWare® International Inc., AusBio Ltd., Grahger Retail Securities Pty Ltd and Starpharma Holdings Ltd. He is a nonexecutive director of Biotron Limited and O'Connell Street Associates.



Clarity's Scientific Advisory Board

Clarity's advisory board comprises global thought leaders with extensive capabilities, expertise and experience in developing radiopharmaceuticals

Prof Oliver Sartor

Prof Richard Wahl

Prof Jason Lewis

Prof Andreas Kjaer

Prof Paul Donnelly

Prof Dale Bailey







The Elizabeth Mallinckrodt
Professor, Chairman of the
Department of Radiology
and Director of the
Mallinckrodt Institute of
Radiology at Washington
University School of
Medicine in St Louis.



The Emily Tow Jackson
Chair in Oncology and
serves as Vice Chair for
Research in the
Department of Radiology
at Memorial Sloan
Kettering Cancer Center
(MSK), Chief of MSK's
Radiochemistry & Imaging
Sciences Service, and
Director of MSK's
Radiochemistry and
Molecular Imaging Probe
Core Facility.



A professor at the
University of Copenhagen
and a chief physician at
the Department of Clinical
Physiology, Nuclear
Medicine & PET at
Rigshospitalet, the
National University Hospital
of Denmark.



The Clarity Group leader of the Donnelly Research Group, The University of Melbourne, based in the state-of-art laboratories of the Bio21 Institute of Molecular Science and Biotechnology.



Principal Physicist in the Department of Nuclear Medicine, Royal North Shore Hospital, Sydney, and Professor in Medical Imaging Sciences at the University of Sydney. Professor Bailev is the former Director of the Sydney Vital Northern Translational Cancer Research Centre at Royal North Shore Hospital and the Flagship Leader of its Neuroendocrine Tumour programme.



Summary

Global leader in Targeted Copper Theranostics (TCT)

- Highly differentiated pipeline of TCT based on ⁶⁴Cu for diagnosis and ⁶⁷Cu for therapy
- TCT address the current manufacturing and logistical limitations in the growth of radiopharmaceuticals
- TCT are scalable, sustainable and dependable to address the growth of radiopharmaceuticals in Oncology
- Broad and defensible IP portfolio of patent families across SAR technology platform, pipeline and products
- Broad pipeline with large and rare indications, with focus on the US FDA
- Well funded with ~\$100M in cash
- Led by an experienced management team and Board with significant years of active involvement in the radiopharmaceutical industry
- Hot sector of the market with numerous recent acquisitions and a limited number of independent clinical-stage radiopharmaceutical companies.



64Cu SAR-bisPSMA PET/CT in mCRPC



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.

