



Managing Director's presentation

Annual General Meeting
24 November 2022

Dr Colin Biggin

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General

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Clarity in a nutshell (ASX:CU6)

Clarity Pharmaceuticals is a clinical stage radiopharmaceutical company developing next-generation products to address the growing need for better diagnostics and treatments in oncology

Proprietary SAR Technology: a true platform technology

Three best-in-class products in clinical development offering high accuracy and precision for both diagnosing and treating disease

Global leader in Targeted Copper Theranostics (TCTs)

Employs copper-64 for diagnosis and imaging and copper-67 for therapy

Significant supply, logistical, dependability and scalability benefits

Mass production on cyclotrons and e-accelerators with finished products having an ideal product shelf life

Environmental advantages over current isotopes

No reliance on nuclear fuel cycle; TCTs do not generate long-lived waste products

Targeted clinical development strategy

Diagnostic products will be the first to reach the market, generating revenue to fund late-stage therapeutic trials

Highly experienced leadership team

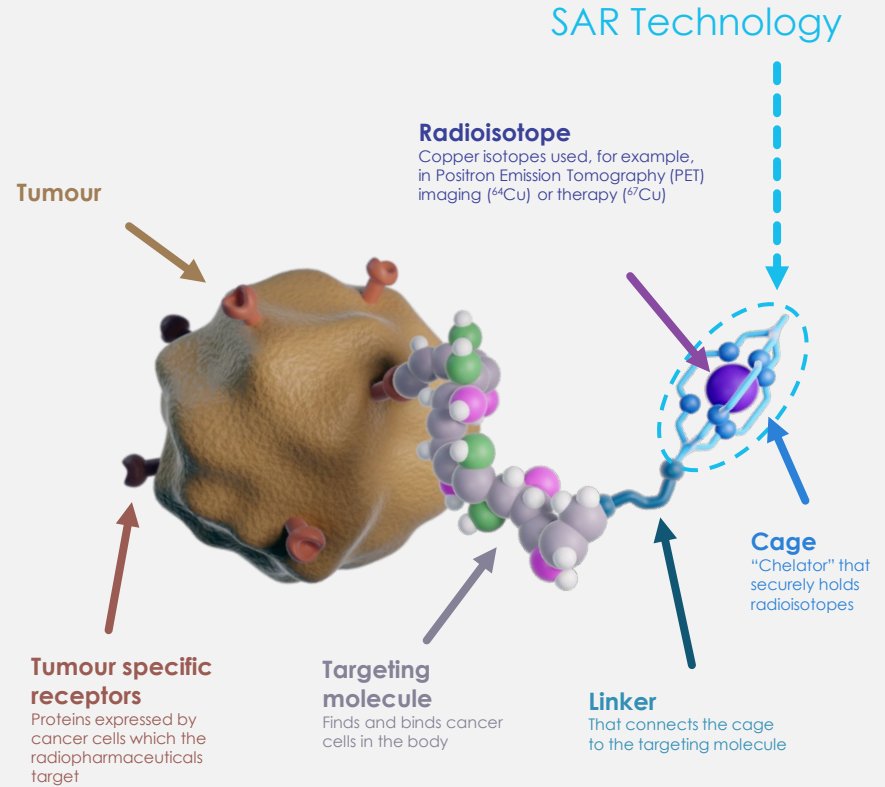
Diverse and in-depth expertise spanning corporate finance, operations, commercialisation & industry

Targeted clinical development strategy



SAR Technology platform

A proprietary, highly specific and highly stable bifunctional cage (chelator) with a superior ability to retain copper isotopes within it and prevent their leakage into the body



Three distinct products built on SAR Technology

Each product area can be a diagnostic or a therapeutic

SAR-bisPSMA

Targets cancers that express Prostate Specific Membrane Antigen (PSMA)

SAR-Bombesin

Targets cancers that express Gastrin Releasing Peptide receptor (GRPr)

SARTATE™

Targets cancers that express Somatostatin receptor 2 (SSTR2)

Each product targets distinct receptors present on the surface of tumour cells across multiple cancers, opening up a range of indications.

Key FY22 highlights

OPERATIONAL

- Actively progressing seven clinical trials of Clarity's three key product areas
- Two investigator-initiated trials (IITs) commenced with Clarity's products
- Enhanced US manufacturing with two additional agreements with Evergreen Theragnostics and 3D Imaging

CORPORATE

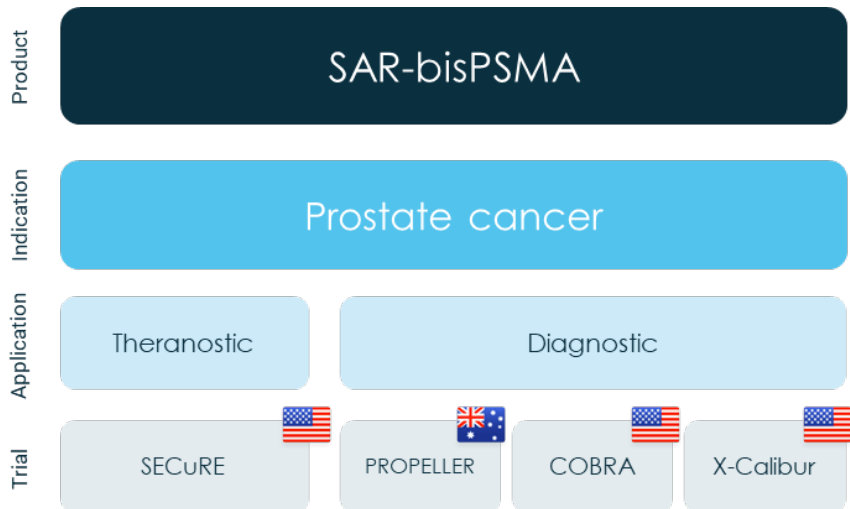
- Strengthened leadership team:
 - New CSO, Dr Jeff Norenberg
 - New CFO, Mr David Green
- Leading experts joined Advisory Board
 - Dr Andrei Iagaru
 - Dr Neal Shore
 - Professor Louise Emmet

FINANCIAL

- Strong cash balance of \$84.7 million as at 30 September 2022
- R&D tax incentive for FY22: ~\$6 million
- ~\$90 million to fund the existing trial pipeline and provide cash runway into 2024

SAR-bisPSMA

Targets the Prostate Specific Membrane Antigen (PSMA), present in the majority of prostate cancers



SECURE - Phase I/IIa



- Recruitment completed for imaging stage
- Advanced to therapy stage with ^{67}Cu SAR-bisPSMA in the US

PROPELLER - Phase I



- Reached full recruitment in July 2022
- Top-line data expected by the end of CY2022
- Results will inform a registrational Phase III trial

COBRA - Phase I/II



- 50% recruitment milestone in October 2022
- First participant imaged in April 2022

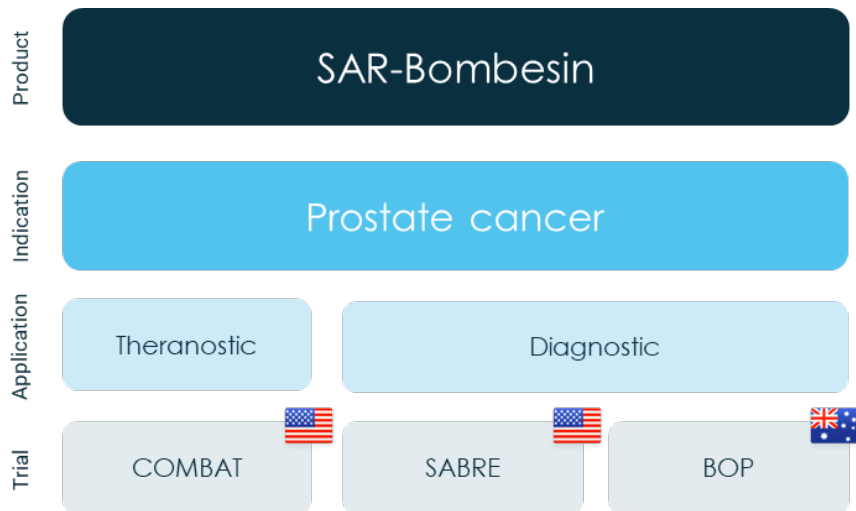
X-Calibur - Phase I/II



- Investigator initiated trial led by Dr Luke Nordquist, Urology Cancer Center and GU Research Network in Omaha, Nebraska

SAR-Bombesin

Targets the Gastrin Releasing Peptide receptor (GRPr), which is present in a number of cancers, including breast and prostate cancers



LATEST NEWS



COMBAT- Phase I/II therapy

- IND application approval received in November 2022 from the US FDA for ^{67}Cu SAR-BBN in PSMA-negative prostate cancer patients
- Site start up activities underway in the US

SABRE – Phase II





- First participants imaged in October 2022
- Recruitment opened for US-based trial in August 2022
- IND application approval received in June 2022 from the US FDA for PSMA-negative prostate cancer patients

BOP – Phase II

- Investigator initiated trial led by Prof Louise Emmett at St Vincent's Hospital Sydney
- 50% recruitment milestone reached in November 2022
- First participants imaged in September 2022

SARTATE

Targets the Somatostatin Receptor 2 (SSTR2), which is present in an aggressive childhood cancer, neuroblastoma, as well as Neuroendocrine Tumours (NETs), among other cancers

Product	SARTATE	
Indication	Neuroblastoma	NETs
Application	Theranostic	Diagnostic
Trial	CL04 	DISCO 

CL04 - Phase I/IIa

- Safety Review Committee recommendation to continue dose escalation phase, opening cohort 3
- Cohort 2 was completed in August 2022
- Cohort 1 was completed in February 2022
- No dose limiting toxicities to date
- Additional US sites opening for recruitment

DISCO – Phase II

- Trial commenced in April 2021
- Recruitment ongoing in Australia



Clarity on clinicaltrials.gov

More details on all our clinical trials are online

Study Title	Conditions	Interventions	Locations
64Cu-SAR-BBN for Identification of Participants With Recurrence of Prostate Cancer (SABRE)	<ul style="list-style-type: none"> Biochemical Recurrence of Malignant Neoplasm of Prostate 	<ul style="list-style-type: none"> Drug 64Cu-SAR-BBN 	<ul style="list-style-type: none"> Stanford University Stanford, California, United States Advanced Molecular Imaging and Therapy Glen Burnie, Maryland, United States Bamf Health, Inc Grand Rapids, Michigan, United States GU Research Network Omaha, Nebraska, United States
64Cu-SAR-bisPSMA for Identification of Participants With Recurrence of Prostate Cancer (COBRA)	<ul style="list-style-type: none"> Biochemical Recurrence of Malignant Neoplasm of Prostate 	<ul style="list-style-type: none"> Drug 64Cu-SAR-bisPSMA 	<ul style="list-style-type: none"> Tower Urology Los Angeles, California, United States Genesis Care Fort Myers, Florida, United States GU Research Network Omaha, Nebraska, United States (and 3 more...)
64Cu-SAR-bisPSMA and 67Cu-SAR-bisPSMA for Identification and Treatment of PSMA-expressing Metastatic Castrate-Resistant Prostate Cancer (SECURE)	<ul style="list-style-type: none"> Prostatic Neoplasms, Castration-Resistant 	<ul style="list-style-type: none"> Drug 64Cu-SAR-bisPSMA Drug 67Cu-SAR-bisPSMA 	<ul style="list-style-type: none"> Mayo Clinic Phoenix, Arizona, United States Tulane Cancer Center, Tulane Medical School New Orleans, Louisiana, United States Johns Hopkins Baltimore, Maryland, United States (and 4 more...)
A Diagnostic Imaging Study of 64Cu-SARTATE Using PET on Patients With Known or Suspected Neuroendocrine Tumors (DISCO)	<ul style="list-style-type: none"> Neuroendocrine Tumors 	<ul style="list-style-type: none"> Drug 64Cu-SARTATE 	<ul style="list-style-type: none"> Nippan Hospital Wingswood, New South Wales, Australia Royal North Shore Hospital Sydney, New South Wales, Australia Royal Adelaide Hospital Adelaide, South Australia, Australia Peter MacCallum Cancer Centre Melbourne, Victoria, Australia
67Cu-SARTATE™ Peptide Receptor Radionuclide Therapy Administered to Pediatric Patients With High-Risk, Relapsed, Refractory Neuroblastoma	<ul style="list-style-type: none"> Neuroblastoma Relapsed Neuroblastoma Refractory Neuroblastoma 	<ul style="list-style-type: none"> Drug 67Cu-SARTATE Drug 64Cu-SARTATE 	<ul style="list-style-type: none"> Phoenix Children's Hospital Phoenix, Arizona, United States Washington University School of Medicine Saint Louis, Missouri, United States Memorial Sloan Kettering Cancer Center New York, New York, United States (and 6 more...)
Positron Emission Tomography (PET) Imaging of Participants With Confirmed Prostate Cancer Using 64Cu-SAR-bisPSMA (PROPELLED)	<ul style="list-style-type: none"> Prostatic Neoplasms 	<ul style="list-style-type: none"> Drug 64Cu-SAR-bisPSMA 	<ul style="list-style-type: none"> Nippan Hospital Wingswood, New South Wales, Australia St. Vincent's Hospital Sydney, New South Wales, Australia GenesisCare CTA, S/OO Medical Clinic Murdoch, Western Australia, Australia
Copper-64 SAR Bombesin in PSMA Negative Prostate Cancer (BOP)	<ul style="list-style-type: none"> Prostate Cancer 	<ul style="list-style-type: none"> Drug: copper-labeled MacCOSar-PEG4-Bombesin 	<ul style="list-style-type: none"> St Vincent's Hospital Sydney, New South Wales, Australia

























Strong focus on US clinical sites, leading cancer centres and investigators



Clinical development in multiple cancers

Clarity's products are progressing through sponsored clinical trials in the US and Australia

Clinical development pipeline as of 24 November 2022

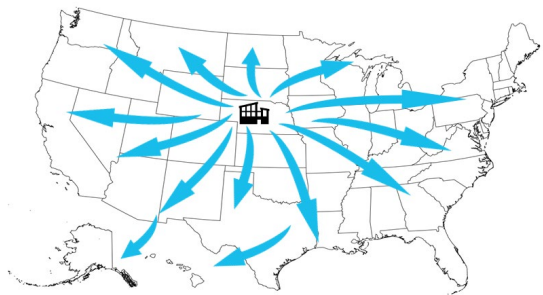
Indication	Product	Application	Current Trial	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Next Milestone
Prostate Cancer	SAR-bisPSMA	Theranostic mCRPC	SECURE						SECURE cohort 1 recruited
	SAR-bisPSMA	Diagnostic in pre-radical prostatectomy	PROPELLER						PROPELLER topline data
	SAR-bisPSMA	Diagnostic in BCR PCa	COBRA						COBRA recruitment complete
	SAR-BBN	Diagnostic in BCR PCa	SABRE						SABRE 50% recruitment
	SAR-BBN	Theranostic	COMBAT						Recruitment commences
Neuroblastoma	SARTATE™	Theranostic	CL04						CL04 1 st patient in cohort 3 recruited
	SARTATE™	Diagnostic							Open IND for NB diagnostic
NETs	SARTATE™	Diagnostic	DISCO						DISCO 50% recruitment
SAR Discovery Platform	Undisclosed	Undisclosed		 	 				
	Undisclosed	Undisclosed		 	 				

Current progress

12 month progress

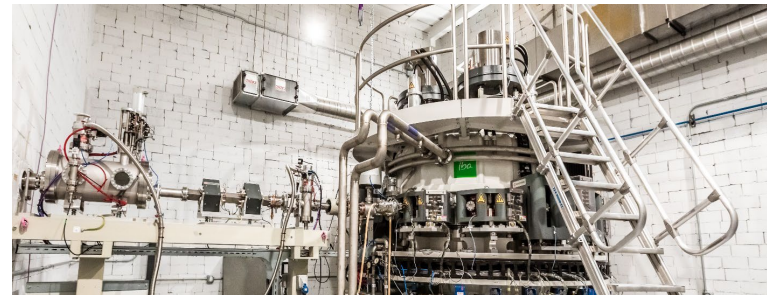
Note clinical development pipeline is indicative only, subject to review. All US studies are conducted under IND

Enabling universal access to PET imaging with ^{64}Cu & the next generation of therapeutics with ^{67}Cu



^{64}Cu (half-life = 12.7h)

- Can be mass produced on cyclotrons with solid targetry
- Every US zip code covered from 1 location
- Patient flexibility with shelf life of up to 48 hours
- Operational flexibility with imaging timepoints up to 72 hours
- Delivered as a ready-to-use cGMP product
- 9-22 times lower exposure than commonly used ^{18}F products
- The ability to centralise investments and supply the country



^{67}Cu (half-life = 2.6 days)

- Commercially available high powered rhodotron with a small footprint
- Scalable with relatively small investments
- Purpose-built supply in the markets of focus, including a US domestic supply
- Only inputs are electricity and Zinc
- No long-lived impurities
- A single rhodotron can produce commercial quantities of ^{67}Cu

Manufacturing

Continuing to build out the large supply chain for TCTs

New collaborations



Production of a range of ready-to-use TCTs for clinical trials



Large scale production of Cu-67 expected early 2023

Patient doses in numbers

In the last 12 months:

- 108 diagnostic doses
- 21 therapy doses

In the last 3 months:

- 48 diagnostic doses
- 7 therapy doses

Robust IP driving the Discovery program

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

Broad Patent Portfolio

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

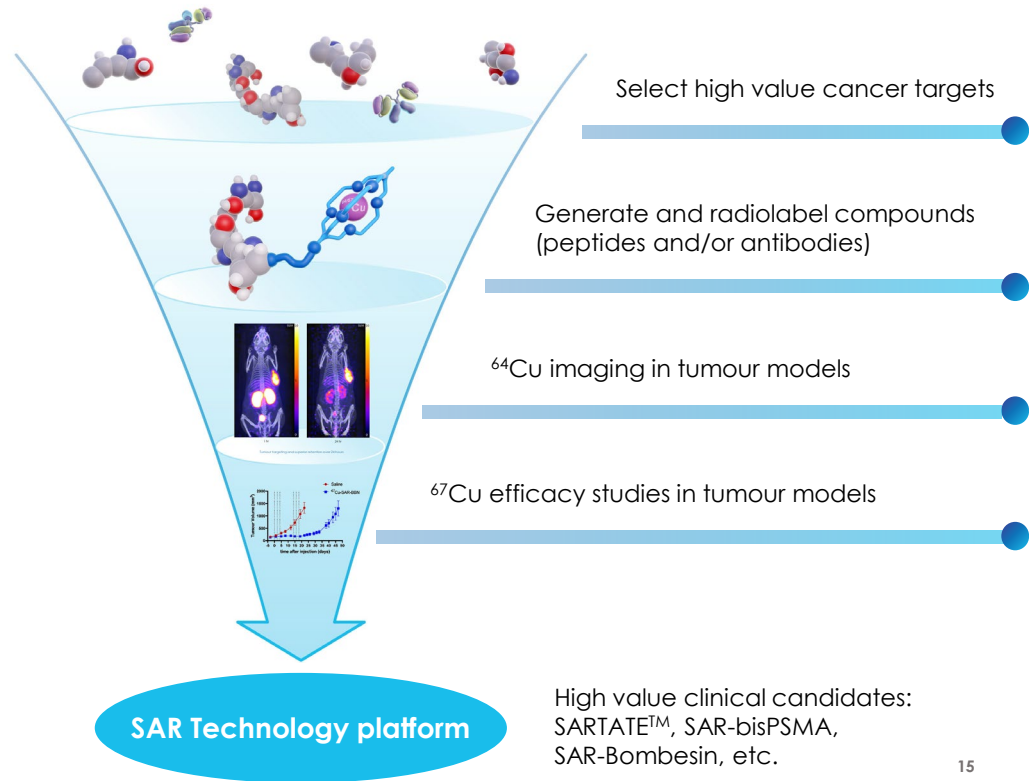
Pipeline Protection

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

Manufacturing & Process Protection

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

Discovery Engine



Highly experienced team



Dr Alan Taylor
Executive Chairman



Dr Colin Biggin
CEO



Michelle Parker
EVP – Global Clinical
Operations



Shaemus Gleason
EVP - Operations



Dr Jennifer Rosenthal
Director of Quality &
Regulatory Affairs



Dr Matt Harris
Director of Technology



Dr Jeff Norenberg
Chief Scientific Officer



Robert Vickery
Company Secretary



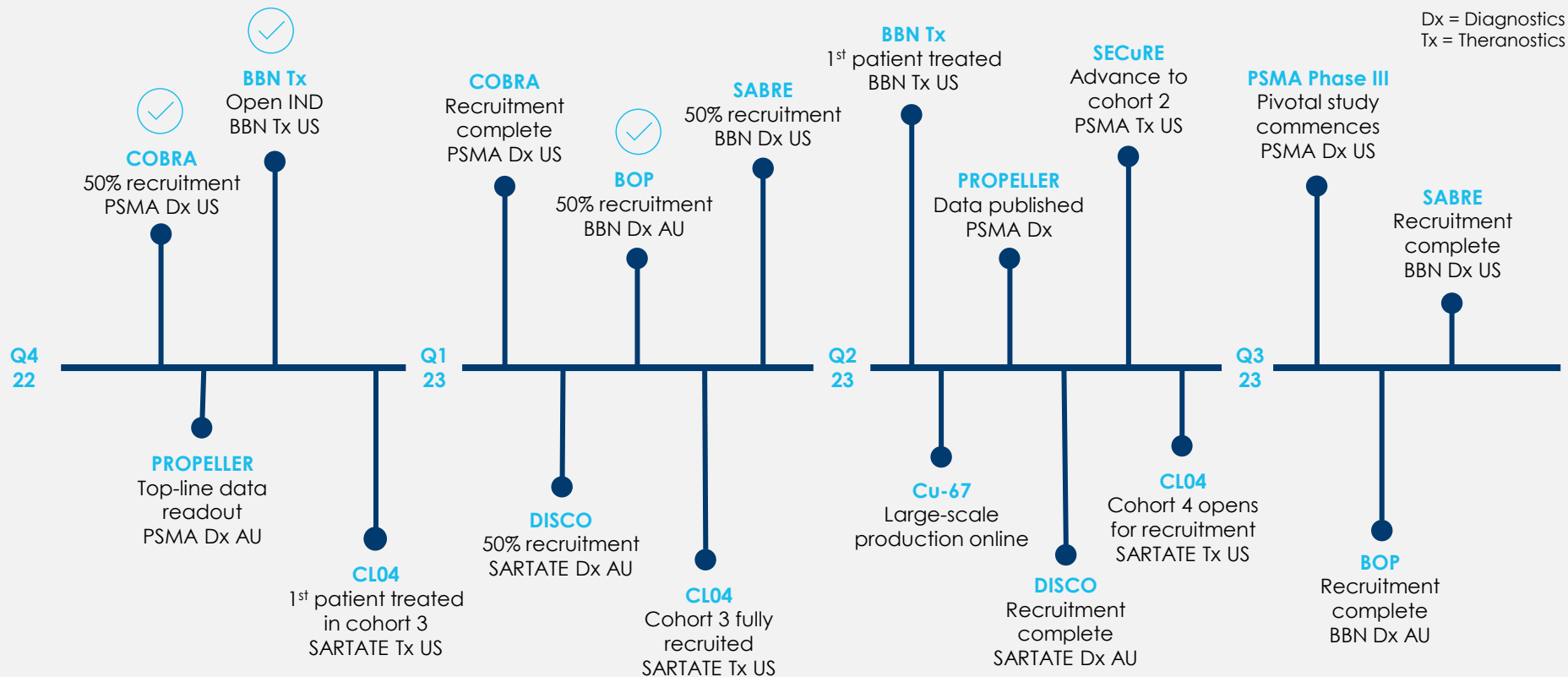
David Green
Chief Financial Officer

Clarity's management team has a diverse and in-depth level of expertise spanning corporate finance, management, operations, commercialisation and industry

- Development, approval and launch of 1st approved radiopharmaceutical therapy product for prostate cancer (Xofigo)
- Decades of experience spanning across science, nuclear medicine/PET, and pharmaceutical industries
- Investment banking experience focused on the life sciences sector



Accelerating clinical progress



Thank you

Contact details

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