



Developing the next-generation of radiopharmaceuticals to improve treatment outcomes for children and adults with cancer

Wilson's Drug and Device Conference

Dr Alan Taylor, Executive Chairman

Dr Colin Biggin, Chief Executive Officer

28 October 2022

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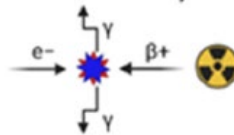
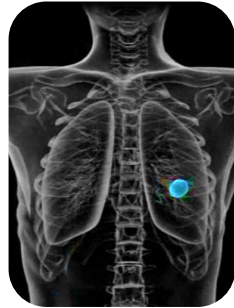
Targeted radiopharmaceuticals are becoming a new pillar of oncology

Radiopharmaceuticals are systemic agents that can be used to diagnose and treat different types of cancer

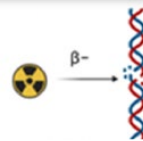
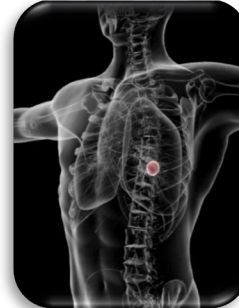
Targeted radiopharmaceuticals use special targeting agents which go to specific receptors on specific cancers. Delivering radiation to the cancer and minimising the off-target effects.

Cu-64 based diagnostics

- Use positron emitting radionuclides to visualise the location of cancers in the body via PET imaging
- Provides information to clinicians on a broad range of areas including identifying disease, monitoring progression and response to therapy.



PET Imaging



Therapy

Cu-67 based therapies

- Use powerful beta emitting radionuclides to damage/kill the cancer cells
- Where therapy is guided by a diagnostic radiopharmaceutical, the term “theranostics” can be used

Recent approved diagnostics:

Pylarify: Q2 22 US sales ~USD130M

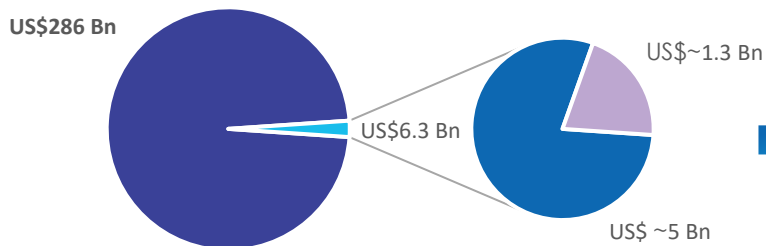
Recent approved therapy:

Pluvicto: Q3* 22 US sales USD80M

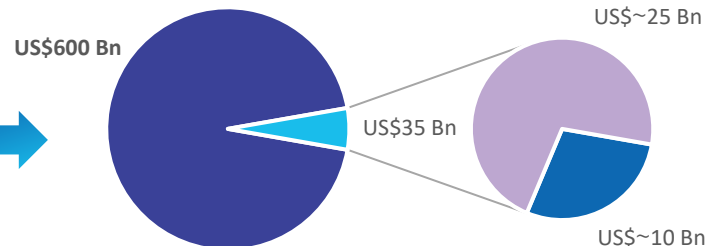
*1st full quarter of product launch

Radiopharmaceuticals: Market overview

Global Oncology Market 2021



Global Oncology Market 2031



- Global Oncology
- Radio-therapeutics
- Global radiopharmaceuticals
- Radio-diagnostics

	2021		2031
Global oncology market	US\$ 286 Billion	➡	US\$ >600 Billion
Global radiopharmaceuticals	US\$ 6.3 Billion	➡	US\$ 35 Billion
Radio-diagnostics	US\$ ~5 Billion	➡	US\$ ~10 Billion
Radio-therapeutics	US\$ ~1.3 Billion	➡	US\$ ~25 Billion

Growth drivers

Radiopharmaceuticals have shown significant growth potential both diagnostically and therapeutically and companies, similar to Clarity, have proven to be very profitable

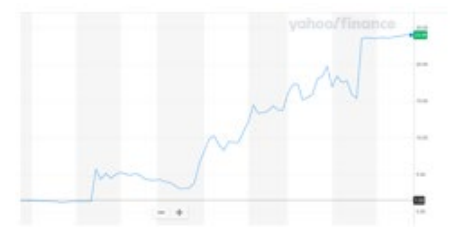
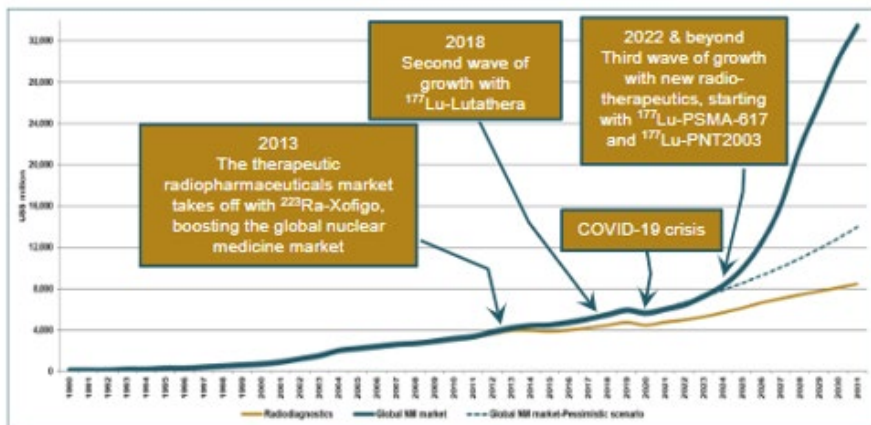
Positive changes

- Re-imburement
- Pricing (Pluvicto >US\$ 250k for 6 doses)
- Broader clinician uptake
- Positive Phase III results for Pluvicto

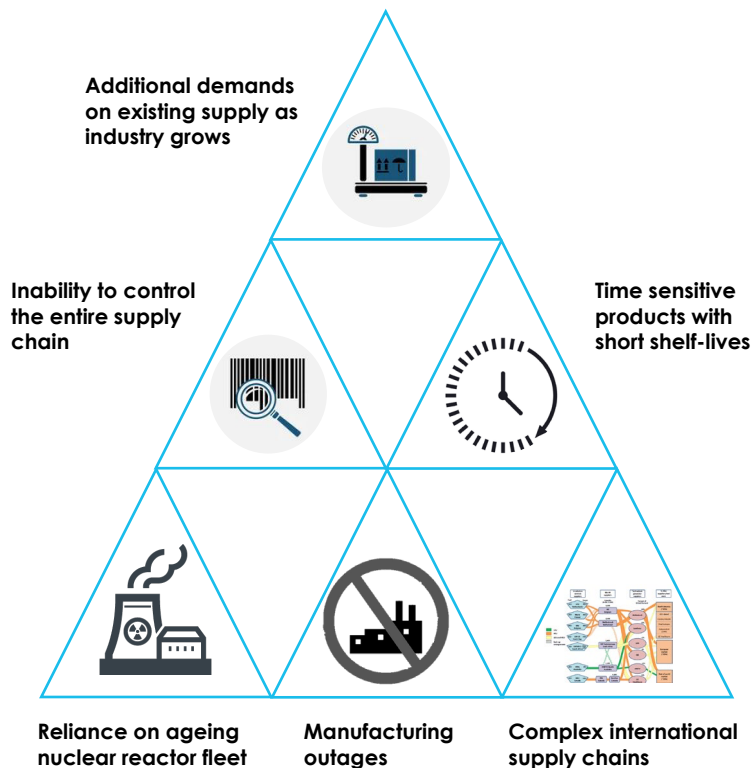
have driven Big Pharma interest in the space

- Novartis
- Bayer

The Nuclear Medicine Market 1990-2031



Current industry challenges



Combined with a history of supply issues

NUCLEAR MEDICINE EUROPE

COMMUNICATION FROM NMEU TO EU OBSERVATORY FOR THE SUPPLY OF MEDICAL RADIOISOTOPES

Global Mo-99 and Tc-99m Production Impacted by Delay of Two Reactors Restarting from Scheduled Maintenance

Brussels, 20 October 2022

NewScientist

SUBSCRIBE AND SAVE 60%

Australia has a huge shortage of the medical isotope needed for scans

HEALTH | 21 September 2019

Bayer Suspends Production of Radium-223 Due to Manufacturing Problem

October 17, 2014

Both hand recordings

[nature](#) > [news](#) > [article](#)

Published: 12 September 2016

Reactor shutdown threatens world's medical-isotope supply

Novartis halts US production of cancer radiotherapies, citing potential quality issues

By Angus LM - May 5, 2022 12:46pm

August 6, 2018

US Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Shortage of Germanium-68/Gallium-68 Generators for the Production of Gallium-68

Dear Dr. Marzella and Dr. Zadecky,

wnn
world nuclear news
— Generating 10 years —

Energy & Environment | New Nuclear | Regulation & Safety | Nuclear Policies | Corporate | Uranium & Fuels

Medical isotope supply chain faces challenges from COVID-19

21 April 2020

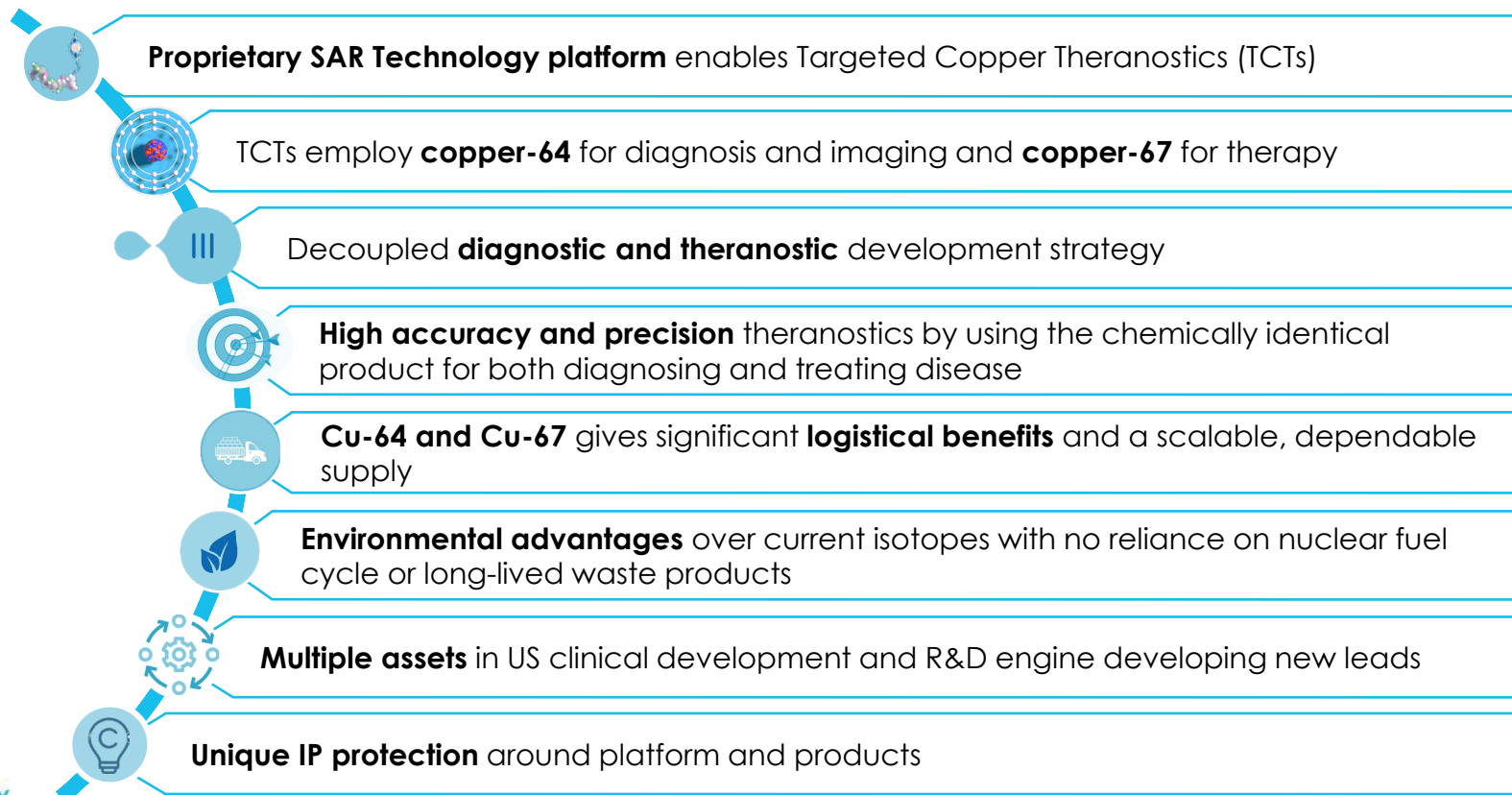
Creates challenges for prescribers

Work to be done to convince oncologists that there is a safe, dependable and reliable source of radiopharmaceutical products.

Without this supply chain, radiopharma may struggle to become a pillar of oncology when its competing with long shelf life oral oncolytics.

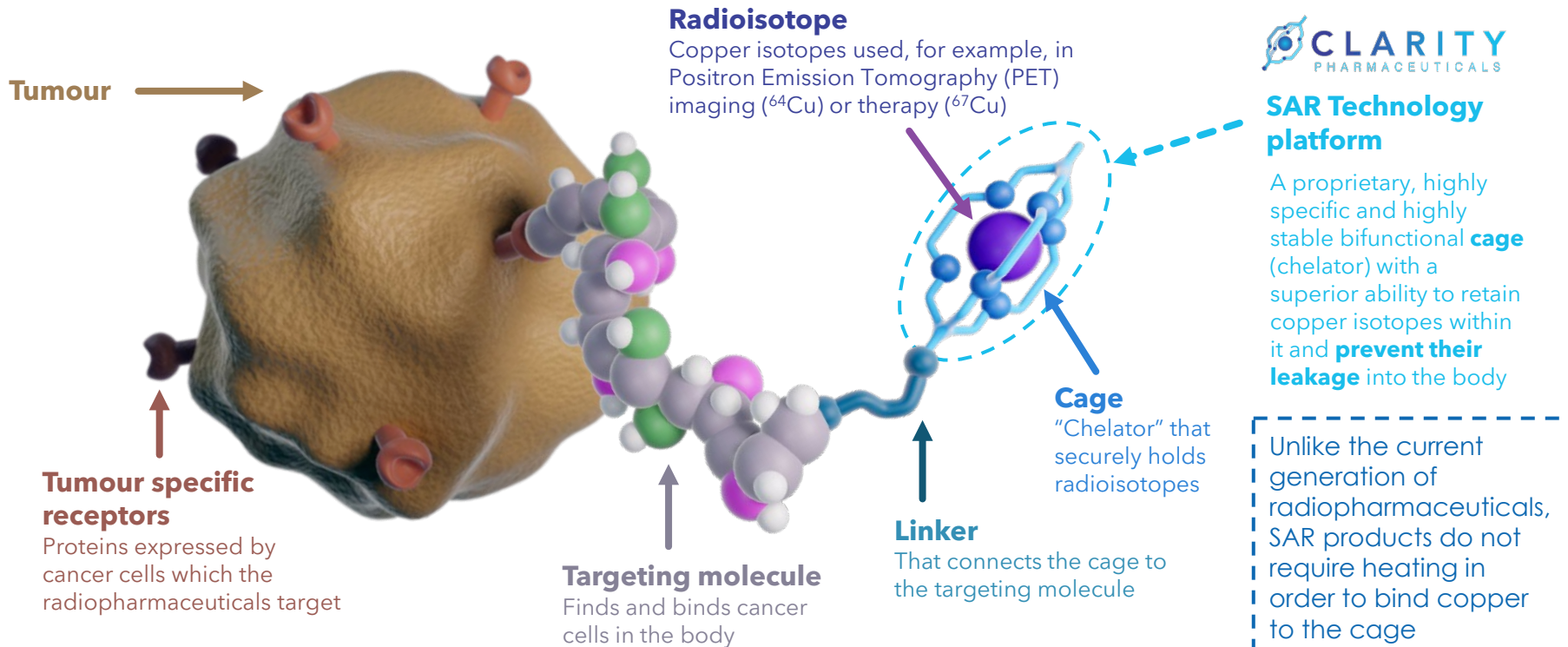
Clarity's TCTs address the current industry challenges

Clarity Pharmaceuticals is a clinical stage radiopharmaceutical company with a mission to develop next-generation products that improve treatment outcomes for children and adults with cancer



Proprietary SAR Technology platform

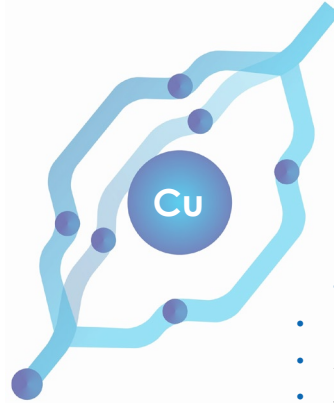
Theranostic radiopharmaceuticals have four main elements: a radioisotope, cage, linker and targeting ligand and are administered intravenously



TCTs: A robust foundation for future growth

Copper-64 (half-life = 12.7 hours)

- Mass produced on cyclotrons
- Every US zip code covered from 1 location
- Patient flexibility with product shelf-life of up to 48 hours
- Operational flexibility with imaging timepoints from 1 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 capital investments and supply entire continents
- Similar half-life to iodine-123 which is routinely produced centrally



Copper-67 (half life = 2.6 days)

- Optimal half-life for peptide-based therapy
- Commercially available high powered rhodotron for mass production 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
- Exclusive supply agreement with NorthStar Medical Isotopes
- **A single rhodotron can produce commercial quantities of ^{67}Cu**
- Similar half-life to yttrium-90, used in SIR-spheres.

Clarity's solution to radiopharmaceutical supply threats

- No time sensitive international supply chains
- No local production requirements (reduced costs and patient safety risk; universal availability)
- Economies of scale from the same manufacturing process
- Ability to quickly integrate new products

The environmental considerations*

- As the number of patient treatments increases, environmental factors will impact the selection of theranostic radiopharmaceuticals
- Production of ^{64}Cu and ^{67}Cu has favorable environmental characteristics, significantly reducing the environmental impact compared to the current generation theranostics based on ^{68}Ga or ^{177}Lu
- This is highly relevant considering the forecasted growth of theranostics over the next decade

*Norenberg J et al. Environmental Considerations Resulting from the Increased Use of Theranostics: Advantages of Targeted Copper Theranostics. Journal of Nuclear Medicine June 2022, 63 (supplement 2) 2655.19. https://jnm.snmjournals.org/content/63/supplement_2/2655

Dual development strategy

SAR Technology enables a synergistic development of stand-alone diagnostics as well as paired theranostics

Diagnostics based on ^{64}Cu

- Broad market opportunities
- Address the current supply and logistical constraints on the industry
- Provide universal access to diagnostic agents
- Short time to market, provides revenue for later stage therapy development
- Low production and distribution costs shield potential revenues from lost of pass-through-status after 3 years in the US



Dx revenue pays for late-stage Tx clinical development

Theranostics based on $^{64}\text{Cu}/^{67}\text{Cu}$

- High precision, high accuracy
- Blockbuster potential for a range of assets
- Easy to scale up
- Domestic US supply
- No reliance on aging nuclear reactors



Marketed Dx re-enforces Tx position

Diagnostic imaging scan with copper-64



Positive for target



Copper-67 therapy

Negative for target



Conventional therapy

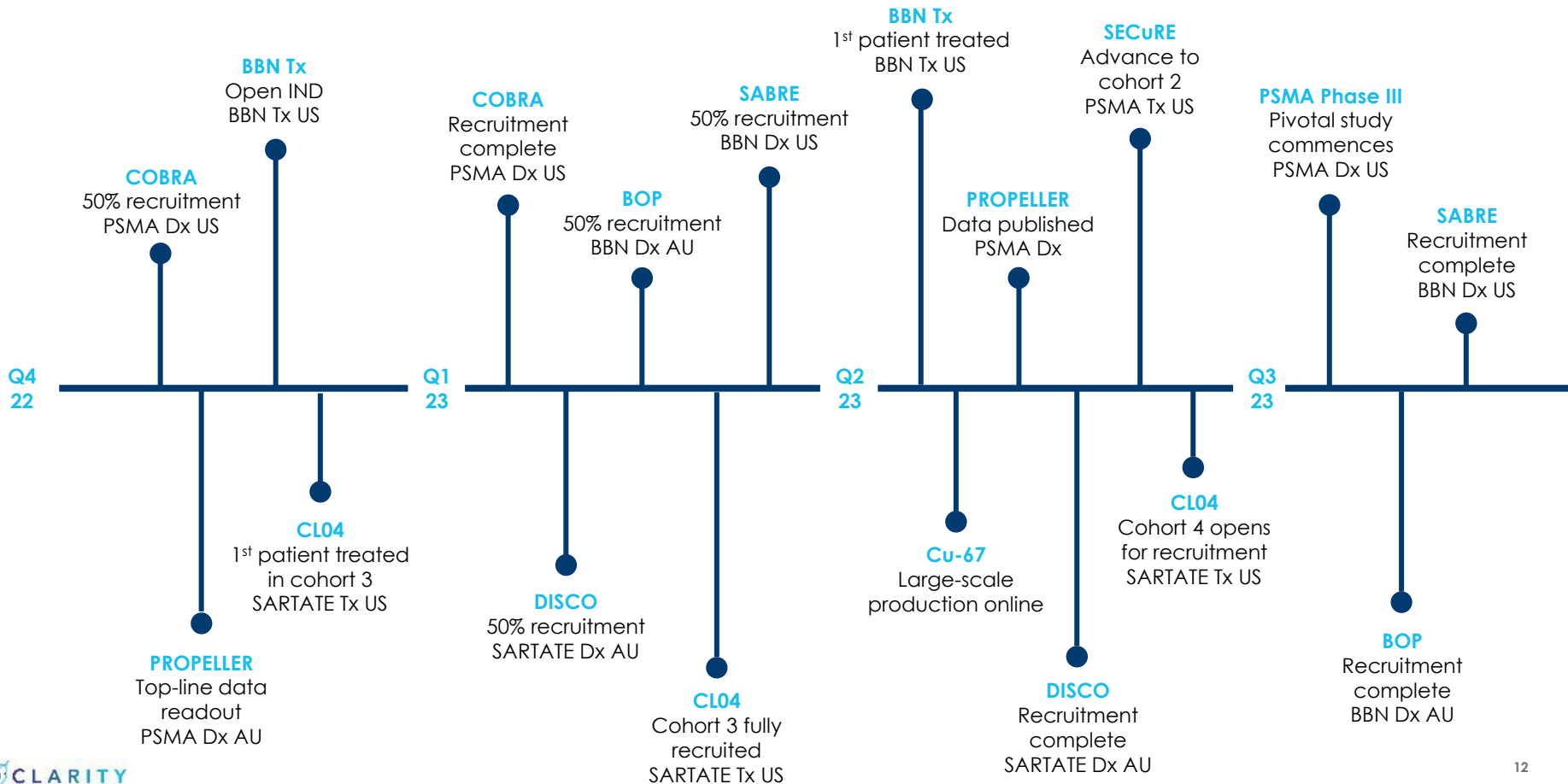
Three core product areas in clinical trials

Clarity has an active clinical development program in multiple oncology indications with unmet needs through a range of products and their applications. The SAR platform is also used in our SAR-DISCOVERY program which has significant synergies with the existing clinical program.

Product	SAR-bisPSMA		SAR-Bombesin		SARTATE™		DISCOVERY
	Cancers that express Prostate Specific Membrane Antigen (PSMA)		Cancers that express Gastrin Releasing Peptide receptor (GRPr)		Cancers that express Somatostatin Receptor 2 (SSTR2)		Developing new products based on Cu-64/Cu-67
Indication	Prostate Cancer				Breast Cancer	Neuroblastoma	NETs
Current trials	Theranostic	Diagnostic	Theranostic	Diagnostic	Diagnostic	Theranostic	Diagnostic
Trial name/phase	SECURE Phase I/IIa	COBRA Phase I/II PROPELLER Phase I	IND expected Q4 Phase I/IIa	SABRE Phase II BOP Phase II IIT	C-BOBCAT Phase I IIT	CL04 Phase I/IIa	DISC Phase II

Inflection points over next 12 months

Dx = Diagnostics
Tx = Therapeutics



Thank you

Contact details

Dr Alan Taylor

Executive Chairman

E: alan.taylor@claritypharm.com

Dr Colin Biggin

Managing Director

E: colin.biggin@claritypharm.com

