



ShareCafe Hidden Gems Webinar

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

Dr Alan Taylor, Executive Chairman

2 December 2022

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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

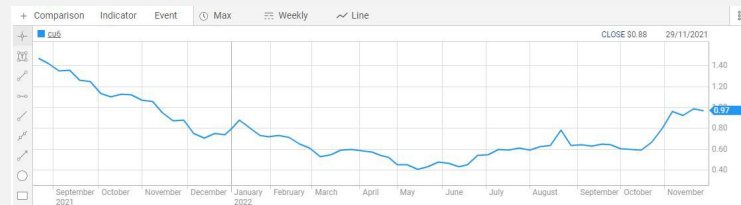
Diagnostic products will be the first to reach the market, generating revenue to fund late-stage therapeutic trials

Highly experienced leadership team

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

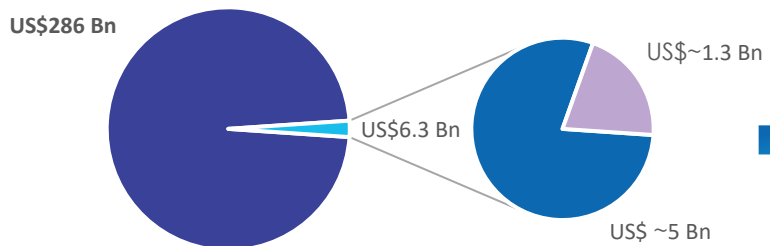
ASX Code: CU6

- Share Price: **\$0.97** as at 1 Dec 2022
- Cash at bank: **\$84.7 million** as at 30 Sep 2022
- R&D tax incentive for FY22: **~\$6 million**
- **~\$90 million** to fund the existing trials and provide cash runway into 2024
- Shares on issue: 258.9 million
- Options on issue: 25.4 million
- Market capitalisation: **\$251 million** (undiluted) as at 1 Dec 2022

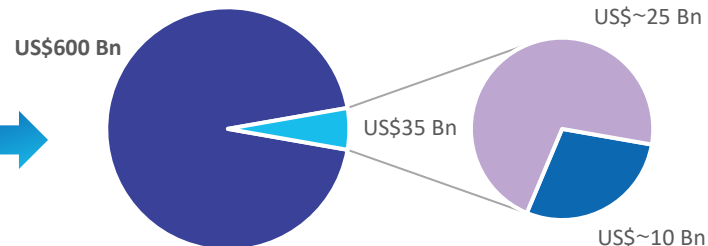


Radiopharmaceuticals: Market overview

Global Oncology Market 2021



Global Oncology Market 2031



- Global Oncology
- Radio-diagnostics

- Global radiopharmaceuticals
- Radio-therapeutics

	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

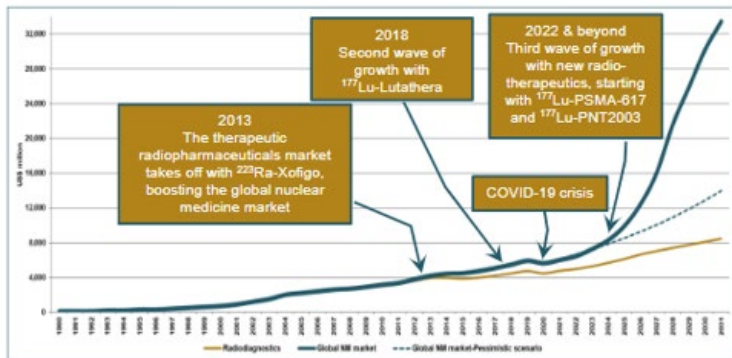
Positive changes

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

have driven Big Pharma interest in the space

- Novartis
- Bayer

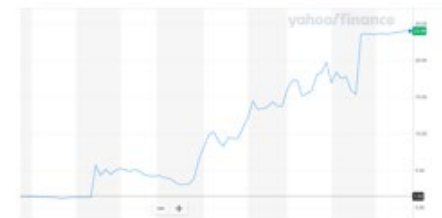
The Nuclear Medicine Market 1990-2031



ALGETA

ENDOCYTE

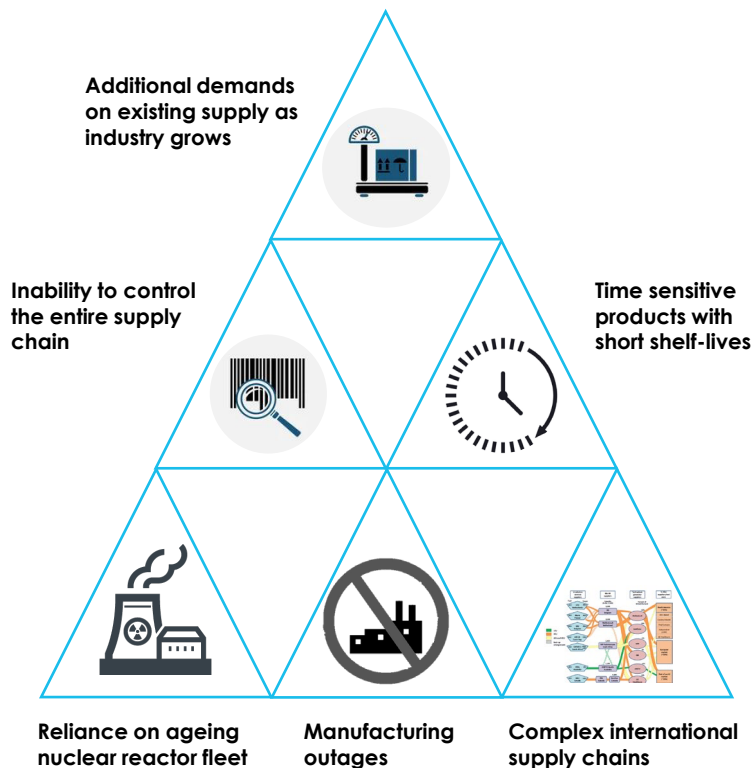
Advanced Accelerator Applications



<p>Recent approved diagnostics: Pylarify: Q3 22 US sales ~USD144M</p>	<p>Recent approved therapy: Pluvicto: Q3 22 US sales USD80M *</p>
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*1st full quarter of product launch

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
Beth Ford Incognito

[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 Angela Liu • May 5, 2012 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,

winn
world nuclear news
Celebrating 15 years

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

Medical isotope supply chain faces challenges from COVID-19

21 April 2020

Creates challenges for prescribers

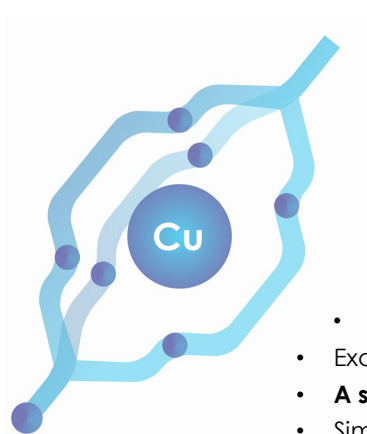
Work to be done to convince oncologists that there is a safe, dependable and reliable source of radiopharmaceutical products.

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

Clarity - the perfect pairing to address current challenges

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*

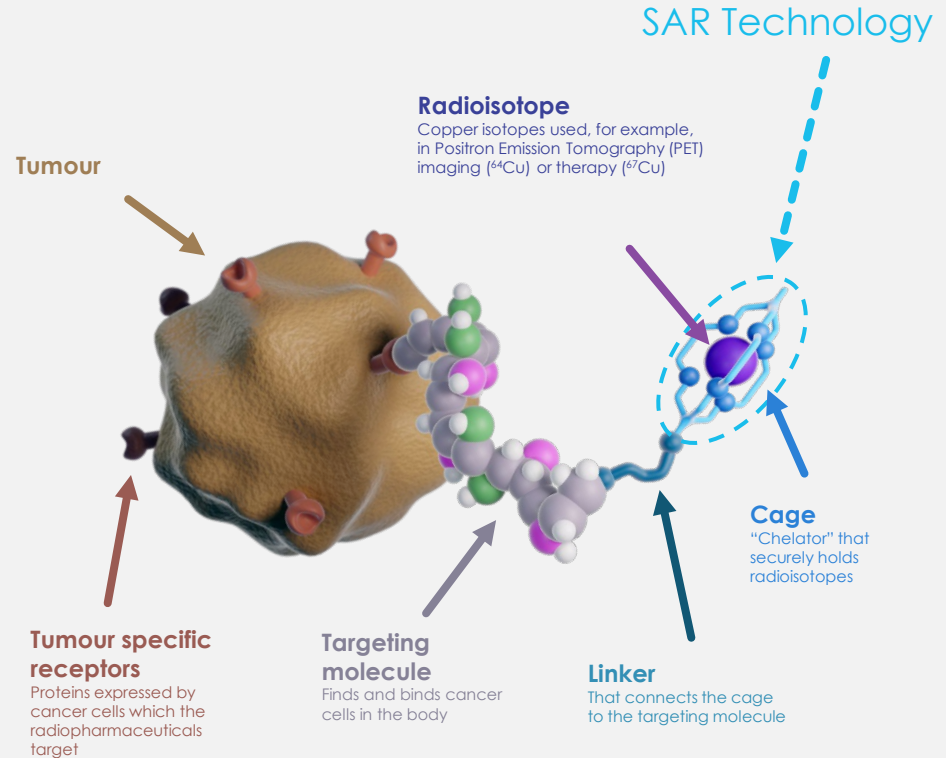
- As the number of patient treatments increases, environmental factors will impact the selection of theranostic radiopharmaceuticals
- Production of ^{64}Cu and ^{67}Cu has favorable environmental characteristics, significantly reducing the environmental impact compared to the current generation theranostics 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

SAR Technology platform

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

- SAR Technology is 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.
- Unlike the current generation of radiopharmaceuticals, SAR products do not require heating in order to bind copper to the cage.



























Clinical Development



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		 	 				

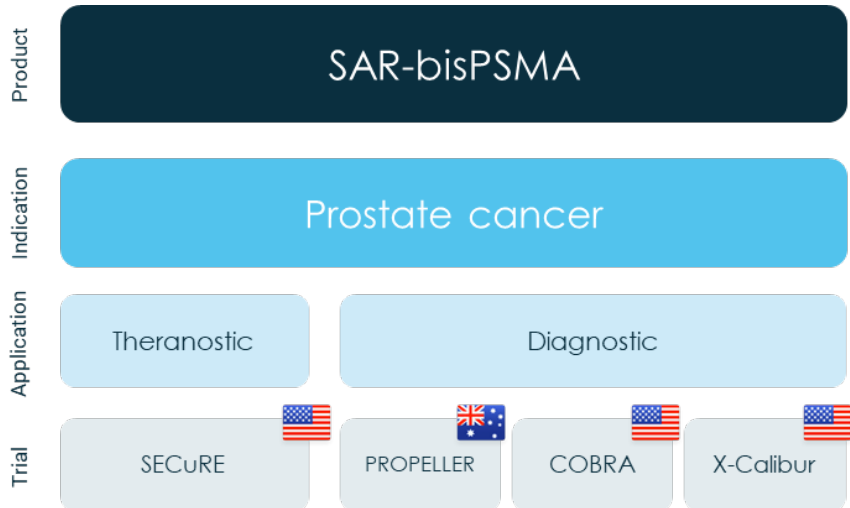
Current progress

12 month progress

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

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 ⁶⁷Cu 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

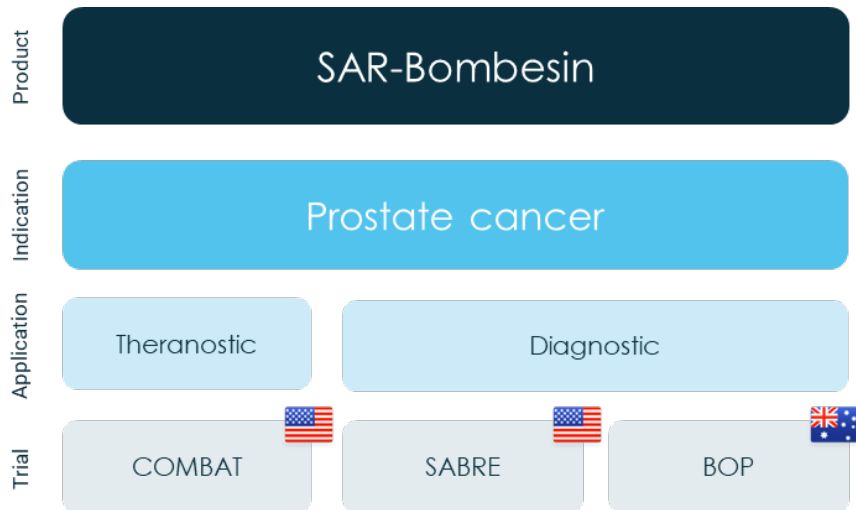
X-Calibur - Phase I/II



- 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

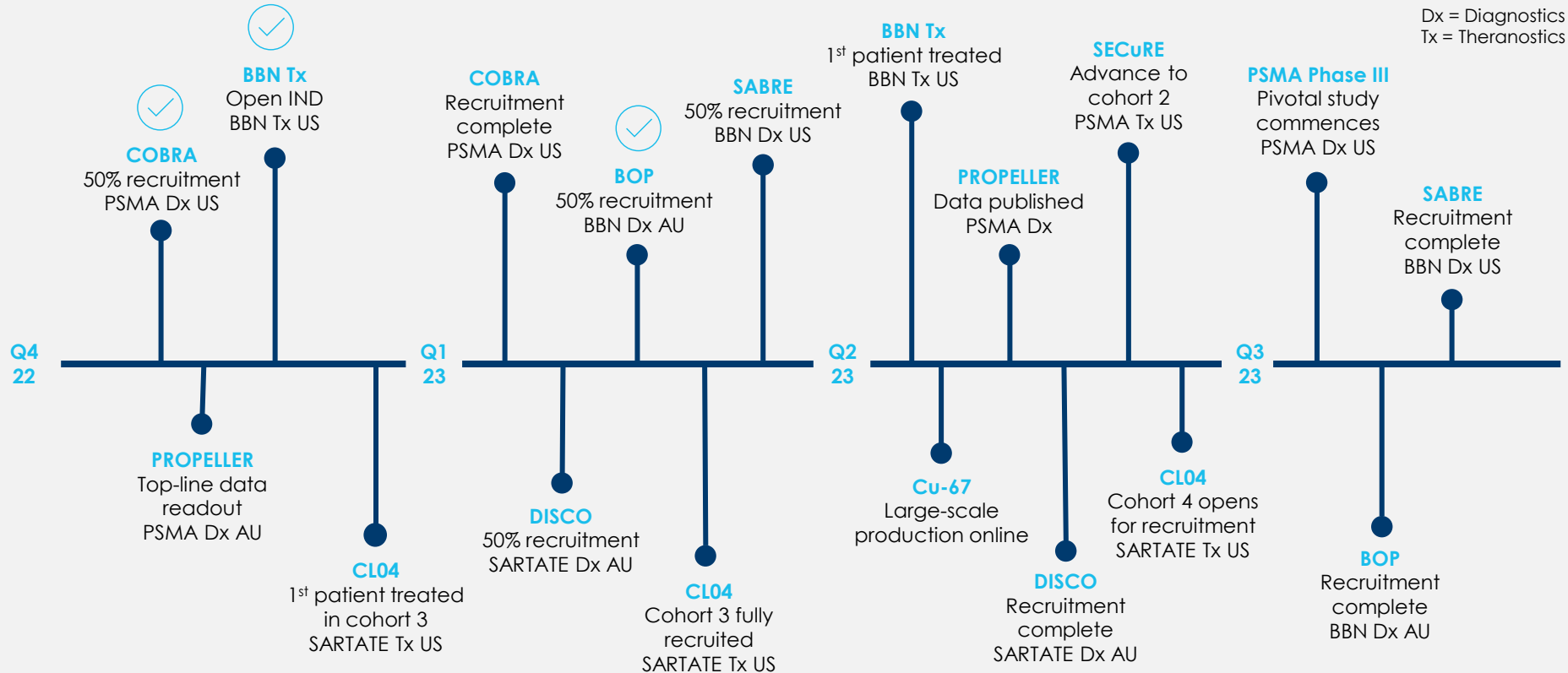
- Safety Review Committee recommendation to continue dose escalation phase, opening cohort 3
- Cohort 2 was completed in August 2022
- Cohort 1 was completed in February 2022
- No dose limiting toxicities to date
- Additional US sites opening for recruitment

DISCO – Phase II

- Trial commenced in April 2021
- Recruitment ongoing in Australia



Accelerating clinical progress



Thank you

Contact details

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