WILSONS

Date 7 December 2022

Theme Company Update

Sector Healthcare

Company

Clarity Pharmaceuticals (CU6)

PROPELLED to upgrade

We maintain our OVERWEIGHT rating on Clarity Pharmaceuticals with a revised price target of $1.22/sh. We view the upcoming release of Clarity's Phase I/II PROPELLER trial results for their ^{64}Cu-SAR-bisPSMA in prostate cancer diagnosis as a de-risking event, with clear signals towards a positive outcome. The readout represents an important step in Clarity's development to a) verify the efficacy of their coupled SAR-copper technology; and b) transition the company into 'pivotal-trial stage', as Clarity move closer towards unlocking revenue to support longer-term programs. Pending the release of these results, we revise our SOTP real-options valuations (ROV), also noting an update to the SAR-Bombesin PSMA-negative prostate cancer trials (for diagnosis and therapy) which see Clarity tracking ~3 years ahead of previous estimates.

Recommendation	**OVERWEIGHT**
12-mth target price (AUD)	$1.22
Share price @ 6-Dec-22 (AUD)	$0.96
Forecast 12-mth capital return	27.9%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	**27.9%**
Market cap ($m)	247.6
Enterprise value ($m)	155.3
Shares on issue (m)	259.3
Sold short (%)	0.0
ASX All Ords weight (%)	0.0
Median turnover/day ($m)	0.1

Key points

Imminent PROPELLER results primed to demonstrate utility of ^{64}Cu-SAR-bisPSMA in the diagnosis of prostate cancer. PROPELLER was designed as a multi-centre, blinded review, dose ranging, non-randomised Phase I study to assess the safety and efficacy of ^{64}Cu SAR-bisPSMA in prostate cancer diagnosis. The trial was planned to enrol 30 participants with confirmed prostate cancer (pre-prostatectomy; typically, partial removal of the prostate gland). We are confident of positive trial results, given safety is bolstered by sound pre-clinical data and broader SAR-copper use validated in NETs, and released preliminary imaging results from the trial demonstrate efficacy of ^{64}Cu-SAR-bisPSMA compared to ^{68}Ga PSMA-11.

Phase III trial set for a sooner-than-expected CY23 commencement. Supported by the IND and data accumulated in their COBRA trial (assessing ^{64}Cu-SAR-bisPSMA in diagnosing biochemical recurrent prostate cancer), Clarity look to begin a Phase III PSMA-prostate cancer diagnostic pivotal trial in CY23. In anticipation of this we look to predicate studies and assess trial/s will likely enrol ~200-400 participants across a ~16-month timeline (akin to Lantheus' Phase II/III OSPREY or CONDOR trials), positioning Clarity to enter the market by the start of FY26E and achieve peak sales of US$136M by FY31.

Model changes. We have de-risked our ROVs for the SAR-bisPSMA diagnostic program from 70% to 100%. Our risk for Phase III and approval/access remains at 75% and 85% respectively. Timelines for Clarity's SAR-Bombesin prostate cancer diagnosis and therapy are both brought forward by ~3 years (to FY26E and FY30 respectively), with the diagnostic trial commencement and enrolment occurring significantly ahead of schedule. The Phase I/IIa BBN therapy program is expected to commence Q2 CY23, with the US IND received recently in November.

Valuation. Following the de-risking of the SAR-bisPSMA diagnostic agent with imminent Phase I/II results and re-adjusting timelines for the SAR-Bombesin PSMA-negative prostate cancer diagnostic (by ~3 years), our 12-month PT is lifted to $1.22/sh. Our PT for Clarity is based on a risked SOTP valuation which utilizes real-options DCF for key pipeline programs; a) prostate $1.01/sh (previously $0.63/sh); b) NB $0.11/sh (previously $0.10/sh); and c) NETs $0.10/sh (previously $0.09/sh). No value is currently attributed to breast cancer Dx program. Unrisked PT is $4.45/share. Clinical readouts in the next 6 months further de-risk valuation by 15% to $1.40/sh.

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12-mth price performance ($)

	1-mth	6-mth	12-mth
Abs return (%)	18.6	101.1	8.5
Rel return (%)	11.7	99.6	8.8

Financial summary (Y/E Jun, AUD)	FY21A	FY22A	FY23E	FY24E	FY25E
EBITDA norm ($m)	(10.2)	(23.8)	(23.9)	(26.5)	(44.9)
Consensus EBITDA ($m)			(26.6)	(32.9)	79.2
EPS norm (cents)	(5.8)	(10.0)	(9.9)	(11.0)	(15.2)
EV/EBITDA (x)	n/m	n/m	n/m	n/m	n/m
FCF yield (%)	(4.6)	(5.0)	(9.7)	(9.9)	(13.8)

Key changes		13-Sep	After	Var %
EBITDA	FY23E	(23.9)	(23.9)	0%
norm	FY24E	(26.5)	(26.5)	0%
($m)	FY25E	(44.9)	(44.9)	0%
EPS	FY23E	(9.9)	(9.9)	-0%
norm	FY24E	(11.0)	(11.0)	-0%
(cents)	FY25E	(14.2)	(15.2)	-7%
Price target		**0.82**	**1.22**	**49%**
Rating		**O/W**	**O/W**	

Source: Company data, Wilsons estimate, Refinitiv, IRESS.
All amounts are in Australian Dollar (A$) unless otherwise stated.

Business Description

Clarity is a clinical stage radiopharmaceutical company developing next-generation theranostic (therapy and imaging) products, based on their proprietary SAR technology. SAR technology unlocks the use of copper isotopes enabling superior imaging and therapeutic characteristics of radiopharmaceutical products. With this combination, Clarity aim to address the current manufacturing and logistical limitations in the growth of the radiopharmaceutical sector in oncology.

Catalysts

a) achievement of trial endpoints; b) partnership opportunities; c) regulatory approvals.

Investment Thesis

We maintain our OVERWEIGHT rating on Clarity Pharmaceuticals with a revised price target of $1.22/sh. We view the upcoming release of Clarity's Phase I/II PROPELLER trial results for their ^{64}Cu-SAR-bisPSMA in prostate cancer diagnosis as a de-risking event, with clear signals towards a positive outcome. Pending the release of these results, we revise our SOTP ROVs, additionally supported by the SAR-Bombesin PSMA-negative prostate tracking ~3 years ahead of schedule.

Risks

a) unfavourable clinical trial results; b) reliance on third parties to advance asset development; c) competitive intensity of radiopharmaceutical market; d) unfavourable markets.

P&L ($m)	FY21A	FY22A	FY23E	FY24E	FY25E
Sales	0.0	0.0	0.0	0.0	0.2
EBITDA norm	(10.2)	(23.8)	(23.9)	(26.5)	(44.9)
EBIT norm	(10.2)	(23.8)	(24.0)	(26.6)	(45.0)
PBT norm	(10.2)	(23.7)	(23.6)	(26.3)	(44.7)
NPAT norm	(10.2)	(23.8)	(23.6)	(26.3)	(44.7)
NPAT reported	(10.4)	(23.8)	(23.6)	(26.3)	(44.7)
EPS norm (cents)	(5.8)	(10.0)	(9.9)	(11.0)	(15.2)
DPS (cents)	0.0	0.0	0.0	0.0	0.0

Growth (%)	FY21A	FY22A	FY23E	FY24E	FY25E
Sales	n/m	n/m	n/m	n/m	n/m
EBITDA norm	45.5	132.8	0.5	10.9	69.2
NPAT norm	45.9	133.2	(0.5)	11.5	69.6
EPS norm (cents)	(80.2)	72.5	(0.5)	11.5	37.3
DPS (cents)	n/m	n/m	n/m	n/m	n/m

Margins and returns (%)	FY21A	FY22A	FY23E	FY24E	FY25E

Interims ($m)	2H21A	1H22A	2H22A	1H23E	2H23E
Sales	0.0	0.0	0.0	0.0	0.0
EBITDA norm	(5.4)	(13.7)	(10.1)	(12.2)	(11.7)
EBIT norm	(5.4)	(13.7)	(10.1)	(12.3)	(11.7)
PBT norm	(5.3)	(13.7)	(10.0)	(12.1)	(11.6)
NPAT norm	(5.3)	(13.7)	(10.0)	(12.1)	(11.6)
NPAT reported	(5.4)	(13.7)	(10.0)	(12.1)	(11.6)
EPS norm (cents)	(3.0)	(5.8)	(4.2)	(5.1)	(4.8)
DPS (cents)	0.0	0.0	0.0	0.0	0.0

Stock specific	FY21A	FY22A	FY23E	FY24E	FY25E
R&D expenditure	(9.7)	(18.9)	(23.5)	(25.0)	(27.7)

Balance sheet ($m)	FY21A	FY22A	FY23E	FY24E	FY25E
Cash & equivalents	18.9	92.3	66.3	39.6	69.7
Current receivables	3.4	6.7	5.0	5.0	5.0
Current inventory	0.0	0.0	0.0	0.0	0.0
PPE	0.1	0.3	0.6	1.0	1.3
Total assets	22.6	99.8	72.5	46.2	76.6
Current payables	1.8	6.8	2.5	2.8	4.2
Total debt	0.0	0.0	0.0	0.0	0.0
Total liabilities	2.3	7.6	2.9	3.4	5.5
Shareholders equity	20.3	92.2	69.6	42.8	71.2

Cash flow ($m)	FY21A	FY22A	FY23E	FY24E	FY25E
Operating cash flow	(7.7)	(13.3)	(25.6)	(26.3)	(44.7)
Maintenance capex	(0.1)	(0.2)	(0.4)	(0.4)	(0.4)
Free cash flow	(7.7)	(13.5)	(26.0)	(26.7)	(45.1)
Growth capex	0.0	0.0	0.0	0.0	0.0
Acquisitions/disposals	0.0	0.0	0.0	0.0	0.0
Dividends paid	0.0	0.0	0.0	0.0	0.0
Other cash flow	(0.7)	(32.1)	12.0	5.0	0.0
Cash flow pre-financing	(8.4)	(45.6)	(14.0)	(21.7)	(45.1)
Funded by equity	20.9	92.1	0.0	0.0	75.2
Funded by cash/debt	(24.0)	(139.0)	26.0	26.7	(105.3)

Liquidity	FY21A	FY22A	FY23E	FY24E	FY25E
Cash conversion (%)	75.6	56.2	108.4	100.1	100.2
Net debt ($m)	(18.9)	(92.3)	(66.3)	(39.6)	(69.7)
Net debt / EBITDA (x)	1.9	3.9	2.8	1.5	1.6
ND / ND + Equity (%)	n/m	n/m	n/m	n/m	n/m
EBIT / Interest expense (x)	n/m	n/m	70.3	n/m	n/m

Valuation	FY21A	FY22A	FY23E	FY24E	FY25E
EV / Sales (x)	n/m	n/m	n/m	n/m	n/m
EV / EBITDA (x)	n/m	n/m	n/m	n/m	n/m
EV / EBIT (x)	n/m	n/m	n/m	n/m	n/m
P / E (x)	n/m	n/m	n/m	n/m	n/m
P / BV (x)	8.3	2.9	3.9	6.3	4.6
FCF yield (%)	(4.6)	(5.0)	(9.7)	(9.9)	(13.8)
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0
Payout ratio (%)	0.0	0.0	0.0	0.0	0.0
Weighted shares (m)	176.5	238.6	238.6	238.6	294.7

Source: Company data, Wilsons estimate, Refinitiv, IRESS.
All amounts are in Australian Dollar (A$) unless otherwise stated.

Preparing for PROPELLER trial results

PROPELLER trial recap

PROPELLER is the first in-human study of ^{64}Cu SAR-bisPSMA. PROPELLER was designed as a multi-centre, blinded review, dose ranging (100 MBq, 150 MBq, 200 MBq), non-randomised Phase I study to assess the safety and efficacy of ^{64}Cu SAR-bisPSMA in prostate cancer diagnosis. The trial aimed to enrol 30 participants with confirmed prostate cancer (pre-prostatectomy; typically partial removal of the prostate gland). Whilst Clarity's PROPELLER trial was completed in Australia, and therefore was not conducted under IND, Clarity's COBRA Phase I/II study assessing ^{64}Cu-SAR-bisPSMA in biochemical recurrent prostate cancer has IND designation, providing a direct pathway towards a US Phase III pivotal trial.

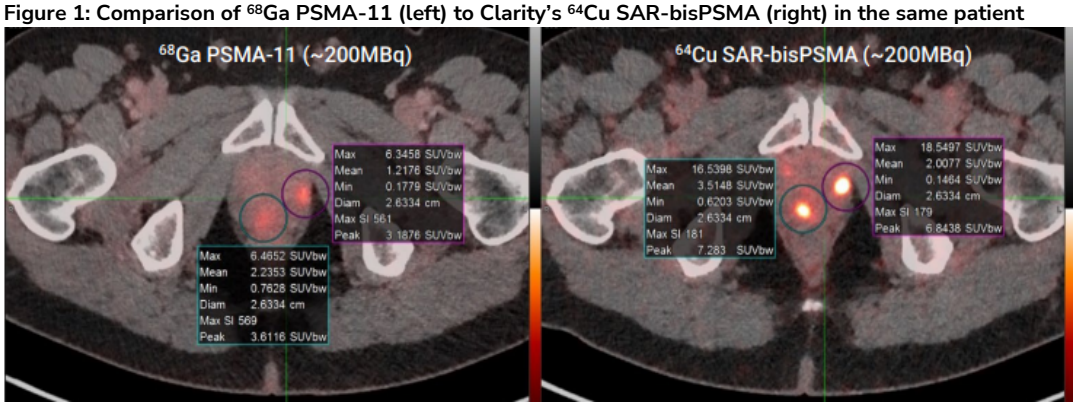
PROPELLER's primary and secondary outcomes.

- Primary outcomes: a) safety and tolerability; b) efficacy in the detection of primary prostate cancer compared to histopathology (biopsy) at 11 weeks. Efficacy measured by the proportion of ^{64}Cu-SAR-bisPSMA PET/CT scans assessed as true positive or false negative.

- Secondary outcomes: a) comparison of image quality at varying dose levels (100 MBq, 150 MBq and 200 MBq); b) comparison of image quality versus ^{68}Ga PSMA-11 (standard of care), assessed by 2 blinded central readers.

Why are we confident on the PROPELLER trial results being positive? We anticipate low probability of any safety/tolerability issues with ^{64}Cu SAR-bisPSMA given positive pre-clinical data[1], no safety issues reported with ^{64}Cu SARTATE in NETs patients[2], and the fact that Clarity's SAR technology prevents copper leakage (an issue previously associated with copper). In terms of efficacy, Clarity released preliminary imaging results from their PROPELLER trial **(Figure 1)** which highlights the enhanced imaging properties of ^{64}Cu SAR-bisPSMA compared to ^{68}Ga PSMA-11, likely a result of their bivalent-designed SAR-bisPSMA molecule which has demonstrated higher tumour uptake in pre-clinical models[1]. Given the release of preliminary imaging results from the PROPELLER trial, and the commencement/continuation of ^{64}Cu SAR-bisPSMA trials in the USA (COBRA, SECuRE), we assess now, that the probability of trial results being negative as very low.

Figure 1: Comparison of ^{68}Ga PSMA-11 (left) to Clarity's ^{64}Cu SAR-bisPSMA (right) in the same patient



Source: Clarity Pharmaceuticals.

PROPELLER should also support transition into a registrational Phase III trial in patients with untreated, confirmed prostate cancer, scheduled for radical prostatectomy (complete removal of the prostate). Clarity's dedication to trial strategy and timelines has been impressive. Following the expected positive read-out of PROPELLER, with the support of the results from their COBRA trial, Clarity will be set up to move into a Phase III trial by CY23 end. We anticipate that Clarity will likely follow a Phase III trial design similar to that of Lantheus/Progenics Phase II/III campaign for PYLARIFY. The design features for the OSPREY trial (primary staging, pre-prostatectomy), specifically best represent our current thinking about Clarity's future ^{64}Cu-SARbisPSMA Phase III. Based on the OSPREY trial, we assess Clarity's Phase III trial will take ~16 months **(Figure 2)**. With the trial expected to commence in 2H CY23 we anticipate market entry by the start of FY26E.

[1]Zia et al. (2019). A Bivalent Inhibitor of Prostate Specific Membrane Antigen Radiolabeled with Copper-64 with High Tumor Uptake and Retention. Angewandte Chemie International Edition, 58(42), 14991-14994

[2]Hicks et al. (2019). 64Cu-SARTATE PET Imaging of Patients with Neuroendocrine Tumors Demonstrates High Tumor Uptake and Retention, Potentially Allowing Prospective Dosimetry for Peptide Receptor Radionuclide Therapy. Journal of nuclear medicine : official publication, Society of Nuclear Medicine, 60(6), 777–785. https://doi.org/10.2967/jnumed.118.217745

We expect, like Lantheus, Clarity will conduct an additional Phase III, which will follow on from their COBRA trial, assessing ^{64}Cu-SARbisPSMA in biochemical recurrent (BCR) prostate cancer. The two clinical trials – PROPELLER and COBRA address the two relevant patient populations that Clarity will target commercially, akin to its competitors. Readout from COBRA is expected in ~Q3 CY23, which should provide further validation, and de-risking of ^{64}Cu SAR-bisPSMA as the Phase III trial is planned to commence.

Figure 2: Design features for Lantheus/Progenics PYLARIFY Phase II/III trials

Study	OSPREY	CONDOR
Trial ID	NCT02981368	NCT03739684
Phase	II/III	III
Actual enrolment	385	208
Start/ Completion date	November 2016 – July 2018	November 2018 – August 2019
Brief summary	Evaluate the safety and diagnostic performance of ^{18}F-DCFPyL injection in patients with high risk prostate cancer who are planned for radical prostatectomy (Cohort A).	Evaluate the diagnostic performance and safety of ^{18}F-DCFPyL PET/CT imaging in patients with suspected recurrence of prostate cancer who have negative or equivocal findings on conventional imaging.
Design	Single group assignment, open label.	Single group assignment, open label.
Primary endpoint	• Specificity of 18F-DCFPyL PET imaging to detect metastatic prostate cancer within the pelvic lymph nodes relative to histopathology in high risk prostate cancer patients. • Sensitivity of 18F-DCFPyL PET imaging to detect metastatic prostate cancer within the pelvic lymph nodes relative to histopathology in high risk prostate cancer patients.	• Correct localisation rate (percentage of participants with a one-to-one correspondence between localisation of at least one lesion identified on 18F-DCFPyL PET and the composite truth standard. • Within 60 days of PET either biopsy/surgery, conventional imaging or locoregional therapy of the suspected lesions was performed.

Source: clinicaltrials.gov, Wilsons.

Valuation

Trial de-risking events increases SOTP risked valuation to $1.22/share

SAR-bisPSMA

With PROPELLER trial results imminent, and on the basis of a high likelihood of positive results, we have de-risked our SAR-bisPSMA diagnostic program Phase I/II from 70% to 100%, increasing program value by 52% **(Figure 3)**. Our risk for Phase III and approval/access remains at 75% and 85% respectively.

In a valuation impact sense, the change in risk to SAR-bisPSMA Dx program adds $0.38/share (+46% vs prior PT), given the significant weighting of the prostate cancer programs on total risked valuation (vs NETs and NB).

Figure 3: SAR-bisPSMA trial de-risking

SAR-bisPSMA Dx	Phase I/II	Phase III	Approval/Access
Estimated probabilities (p)	70%	75%	85%
Estimated timing	15/12/2022	1/11/2024	1/09/2025
R&D costs (A$m)	15.0	20.0	8.0
S+ (upside values, A$m)	151.0	241.7	308.4
S (start of phase value)	104.8	151.0	241.7
Real option values (A$m)	**72.5**	**126.0**	**233.7**

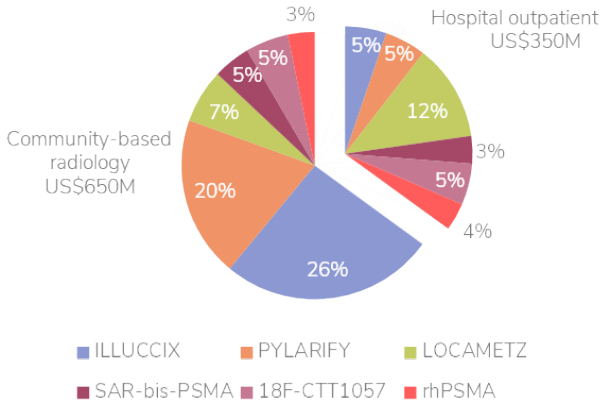
SAR-bisPSMA Dx	Phase I/II	Phase III	Approval/Access
Estimated probabilities (p)	100%	75%	85%
Estimated timing	15/12/2022	1/11/2024	1/09/2025
R&D costs (A$m)	15.0	20.0	8.0
S+ (upside values, A$m)	151.0	241.7	308.4
S (start of phase value)	149.8	151.0	241.7
Real option values (A$m)	**110.0**	**126.0**	**233.7**

Source: Wilsons estimates.

Peak sales estimates. We model global peak net sales of US$136m for SAR-bisPSMA in prostate cancer diagnosis which assumes 12% share of the market (FY31E). In **Figure 4,** we summarise our ~US$1B market share assumptions for the diagnostic agents expected on the market in FY28E. Our modest share assumptions are based on Clarity entering the market as the sixth player. Upside in this valuation will likely be due to expansion in the overall TAM (management, intraoperative use etc.), and, if SAR-bisPSMA is able to demonstrate clear benefits (logistical or clinical) to already approved products.

SAR-bisPSMA will be used as a validation asset. SAR-bisPSMA represents by far the biggest opportunity for Clarity incidence-wise, which should see widespread validation of their SAR-copper technology and more importantly, reason to believe that further investment into commercial production of copper, is warranted, given the size of the indication and ongoing issues with the traditionally used isotopes. We assess that SAR-bisPSMA will also be used to generate early revenue for Clarity (FY26E onwards) which should provide funding for the development of their larger therapy programs.

Figure 4: Predicted market shares for PSMA-directed PET/CT agents across hospital and radiology settings (FY28E)



Source: Wilsons.

SAR-Bombesin

Timelines for the SAR-BBN diagnostic and therapy programs are brought forward by ~3 years. Our original estimates for SAR-BBN in prostate cancer diagnosis were predicated on the company prioritising other programs (PSMA-positive prostate cancer therapy) and thus were delayed due to capital allocation. Clarity has demonstrated their commitment to their pipeline development which should see their SAR-BBN diagnostic on-market by FY26E end (originally FY30E) and their therapy by FY30E end (originally FY32E). The shifts in timeline increase the value of the diagnostic program by 63% and the therapy program by 34%.

Clarity driven by trial readouts in 2023

Four readouts expected across the next year. In **Figure 5 overleaf,** we provide an updated summary of Clarity's registered clinical trials, which highlight the four trial-readouts in the next 12 months. These include the imminent PROPELLER trial, Neuroblastoma theranostic trial (CL04), US-based PSMA diagnostic trial (COBRA) and NETs diagnostic trial (DISCO). Current timing puts the first read-out of Clarity's larger-scale trial of SAR-Bombesin in PSMA-negative prostate cancer in ~January 2024, however we note the addition of further registered sites which may bring forward enrolment, adding a fifth trial readout across the next year. These represent significant de-risking points for the stock as Clarity moves from an early Phase I/II stage company into a Phase II-pivotal trial inflection point.

Figure 5: Summary of Clarity's registered clinical trials in order of expected readouts

Title	Status	Conditions	Characteristics	n	Dates
Positron Emission Tomography (PET) Imaging of Participants With Confirmed Prostate Cancer Using 64Cu-SAR-bisPSMA (PROPELLER)	Active, not recruiting	• Prostatic Neoplasms	Phase: Phase I Outcome Measures: • Safety and tolerability of 64Cu-SAR- bisPSMA using Common TerminologyCriteria for Adverse Events. • Efficacy of 64Cu-SAR-bisPSMA in theDetection of Primary Prostate Cancer Compared to Histopathology • Comparison of image quality at varyingdose levels of 64CuSAR-bisPSMA for each dose cohort (100 MBq, 150 MBq and 200 MBq).	30	Primary Completion: August 2022 Study Completion: August 2022 Study Read-out: December 2022
67Cu-SARTATE™ Peptide Receptor RadionuclideTherapy Administered to Pediatric Patients With High-Risk, Relapsed, Refractory Neuroblastoma (CL04)	Recruiting	• Neuroblastoma • Relapsed Neuroblastoma • Refractory Neuroblastoma	Phase: • Phase I • Phase II Outcome Measures: • Maximum Tolerated Dose (MTD) of67Cu-SARTATE • Safety and tolerability of Cu-67 SARTATE using Common Terminology Criteria for AdverseEvents (CTCAE) • Safety and tolerability of Cu-64SARTATE using CTCAE • Overall response rate/Best response	34	Primary Completion: December 2028* Study Completion: December 2028* Study Read-out: April 2023 **Long-term follow-up associated with therapy*
64Cu-SAR-bisPSMA for Identification of Participants With Recurrence of Prostate Cancer (COBRA)	Recruiting	• Biochemical Recurrence of Malignant Neoplasm of Prostate	Phase: • Phase I • Phase II Outcome Measures: • Incidence and severity of 64Cu- SAR-bisPSMA Treatment-Emergent Adverse Events and Serious Adverse Events [Safety and Tolerability] • Participant-level correct detection rate • Region-level positive predictive value	50	Primary Completion: April 2023 Study Completion: April 2023 Study Read-out: July 2023
A Diagnostic Imaging Study of 64Cu-SARTATE Using PET on Patients With Known or Suspected Neuroendocrine Tumors (DISCO)	Recruiting	• Neuroendocrine Tumors	Phase: Phase II Outcome Measures: • Comparison of diagnostic performanceof 64Cu-SARTATE to that of 68Ga- DOTATATE on a per-lesion basis for discordant findings • To assess the proportion of concordance between 4-hour 64Cu-SARTATE to that of 68Ga-DOTATATE • To compare the diagnostic performance of 64Cu-SARTATE to 68Ga-DOTATATE on a per-participantbasis in participants with suspected disease only. • Incidence of adverse events related to64Cu-SARTATE	63	Primary Completion: August 2023 Study Completion: August 2023 Study Read-out: November 2023
64Cu-SAR-BBN for Identification of ParticipantsWith Recurrence of Prostate Cancer (SABRE)	Recruiting	• Biochemical Recurrence of Malignant Neoplasm of Prostate	Phase: Phase II Outcome Measures: • Incidence and severity of 64Cu-SAR-BBN Treatment-Emergent Adverse Events and Serious Adverse Events [Safety and Tolerability] • Participant-level correct detection rate • Region-level positive predictive value	50	Primary Completion: October 2023 Study Completion: October 2023 Study Read-out: January 2024

Source: Clinicaltrials.gov, Clarity, Wilsons.

Figure 5 continued overleaf.

Figure 5 continued. Summary of Clarity's registered clinical trials in order of expected readouts

Title	Status	Conditions	Characteristics	n	Dates
Copper-64 SAR Bombesin in PSMA NegativeProstate Cancer (BOP)	Recruiting	• Prostate Cancer	Phase: Phase II Outcome Measures: • Explore the diagnostic potential of 64Cu-SAR-BBN PET In men with rising PSA and negative PSMA PET inthe 2 cohorts • To assess the diagnostic value of64Cu-SAR-BBN PET • To evaluate 64Cu-SAR-BBN PETquantitative findings • To determine the optimal timing forimaging post BBN injection	30	Primary Completion: September 2023 Study Completion: June 2024 Study Read-out: September 2024
64Cu-SAR-BBN and 67CU SAR-BBN for Identification and Treatment of Gastrin ReleasingPeptide Receptor (GRPR)-Expressing MetastaticCastrate Resistant Prostate Cancer in Patients Who Are Ineligible for Therapy With 177Lu-PSMA-617 (COMBAT)	Not yet recruiting	• Prostatic Neoplasms • Castration-Resistant	Phase: • Phase I • Phase II Outcome Measures: • Maximum tolerated dose (MTD) or maximum feasible dose (MFD) of asingle dose of 67Cu-SAR-BBN • Recommended dose of two doses of67Cu-SAR-BBN • Efficacy of 67Cu-SAR-BBN in termsof Prostate Specific Antigen (PSA) response/radiographic response • Incidence of dose limiting toxicities [Safety and tolerability] of 67Cu-SAR-BBN • Safety and tolerability of 67Cu-SAR-BBN: Number of Participants with changes from baseline in vital signs	38	Primary Completion: May 2026 Study Completion: May 2026 Study Read-out: November 2026
64Cu-SAR-bisPSMA and 67Cu-SAR-bisPSMA for Identification and Treatment of PSMA-expressing Metastatic Castrate Resistant Prostate Cancer (SECuRE)	Recruiting	• Prostatic Neoplasms, Castration-Resistant	Phase: • Phase I • Phase II Outcome Measures: • Biodistribution/dosimetry of 64Cu-SAR-bisPSMA • Modelling of 67Cu-SAR-bisPSMAdosimetry utilizing the 64Cu-SAR-bisPSMA PET/CT scans • Maximum Tolerated Dose (MTD) or Maximum Feasible Dose of a singledose of 67Cu-SAR-bisPSMA • Recommended dose of two doses of 67Cu-SAR-bisPSMA • Efficacy of 67Cu-SAR-bisPSMA interms of Prostate specific Antigen (PSA) response/radiographic response • Safety and tolerability of 67Cu-SAR- bisPSMA: Number of Participants With Changes from baseline in Vital Signs	44	Primary Completion: September 2026 Study Completion: September 2026 Study Read-out: February 2027

Source: Clinicaltrials.gov, Clarity, Wilsons.

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