WILSONS

Date 14 February 2023

Theme Company Update

Sector Healthcare

Company

Clarity Pharmaceuticals (CU6)

Clarity's copper play stacks up vs new SOC

We maintain our OVERWEIGHT rating on Clarity Pharmaceuticals and risked price target of $1.22/sh. Clarity have unveiled further detail from their Phase I/II PROPELLER trial with their prostate cancer diagnostic asset - ^{64}Cu-SAR-bisPSMA. Clarity announced in December the trial hit its primary endpoints, however today we see further detail regarding the safety profile and accuracy of the diagnostic versus the new standard of care (^{68}Ga-PSMA-11). Whilst this asset may only arrive as a 6th market product (following dominant franchises from Telix, Lantheus & Novartis) there is greater inherent value in this trial readout than the future revenues this asset may generate. Demonstrating the superior efficacy of Clarity's copper based Dx (with associated convenience benefits) to existing approved SOC products, speaks to the potential of their broader Cu-based pipeline focused on ^{64}Cu and ^{67}Cu alone, to bring the same benefits to indications with less competitive tension (i.e. Neuroblastoma, NETs, PSMA-negative prostate cancer).

Recommendation	OVERWEIGHT
12-mth target price (AUD)	$1.22
Share price @ 14-Feb-23 (AUD)	$0.77
Forecast 12-mth capital return	60.0%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	**60.0%**

Market cap ($m)	102.6
Enterprise value ($m)	10.3
Shares on issue (m)	134.1
ASX All Ords weight (%)	0.0
Median turnover/day ($m)	0.2

Key points

Standard of Care (SOC) now ^{68}Ga-PSMA-11. Both Telix and Novartis used data comparing ^{68}Ga-PSMA-11 PET to conventional CT with ^{99}Tc bone scanning as the existing SOC to support marketing authorizations for ILLUCCIX and LOCAMETZ respectively in primary staging. This has now changed in the advent of their approval, hence the comparison made in PROPELLER to these agents. The proPSMA study is our best comparator for ^{68}Ga-PSMA-11 accuracy outside of the PROPELLER trial, noting key differences in study design/cohort inclusion (larger n=300 parallel design vs n=30 within subject control; inclusion of PSA >20ng/ml for proPSMA vs >10ng/ml for PROPELLER). Data below…

Clarity's diagnostic shows superiority over SOC. We caveat these findings by the early stage of the study and limited data presented, but note Clarity's agent had higher detection accuracy across both blinded reviewers than the new SOC, being ^{68}Ga-PSMA-11. Averaging the two blinded readers suggests ~93% accuracy in detection for ^{64}Cu-SAR-bisPSMA versus ~81% for SOC, based on each participant being scanned with both agents and then being confirmed by histopathology. We note in proPSMA ^{68}Ga-PSMA-11 achieved 92% accuracy (but as noted above, trial differences make this a poor like-for-like vs within PROPELLER). No comparison to PYLARIFY (^{18}F-based) was made. Importantly the ^{64}Cu agent detected confirmed secondary disease in one patient that was missed with ^{68}Ga agent demonstrating clinical utility differences.

PROPELLER results support Phase III progression. Clarity have announced Phase III plans are underway for advancement of their ^{64}Cu-SAR-bisPSMA diagnostic. We understand the trial design will be similar to that of Lantheus' OSPREY study in pre-prostatectomy patients, with some differences (which we have previously summarised here). Briefly, between 200-400 participants taking ~16-months could be likely, positioning CU6 for an FY26e market entry, with our peak sales estimate of US$136M (FY31e) assuming 12% capture of the TAM.

Valuation. We maintain our risked SOTP valuation of $1.22/sh comprising a) prostate $1.01/sh; b) Neuroblastoma $0.11/sh; and c) NETs $0.10/sh. No value is currently attributed to breast cancer. Unrisked PT is $4.45/sh. Further clinical readouts in the upcoming 3-10 months further de-risk our valuation by 15% to $1.40/sh provided positive results are achieved (detailed in note p4).

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12-mth price performance ($)

	1-mth	6-mth	12-mth
Abs return (%)	(9.9)	46.6	20.1
Rel return (%)	(15.0)	37.2	15.1

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)	93.3
EPS norm (cents)	(5.8)	(10.0)	(9.9)	(11.0)	(15.1)
EV/EBITDA (x)	n/m	n/m	n/m	n/m	n/m
FCF yield (%)	(5.1)	(5.6)	(10.7)	(11.0)	(15.2)

Key changes		7-Dec	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	(15.2)	(15.1)	1%
Price target		1.22	1.22	0%
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.

Investment Thesis

We maintain our OVERWEIGHT rating on Clarity Pharmaceuticals and risked PT of $1.22/sh. Further PROPELLER data demonstrates the benefits of copper-based PET agents in image detection and accuracy, which Clarity will look to solidify in follow-on Phase II/III programs.

Catalysts

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

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)	(15.1)
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	36.5
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)	7.5	2.6	3.5	5.7	4.2
FCF yield (%)	(5.1)	(5.6)	(10.7)	(11.0)	(15.2)
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	296.5

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

PROPELLER demonstrates superiority of Copper

PROPELLER recap & results detail

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 (BCR) 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 two blinded central readers.

New data

Safety data. The agent was shown to be safe and well tolerated. 1 patient of 30 reported a mild/Grade 1 (lowest level) adverse event being a metallic taste in the mouth. We did not anticipate material safety or tolerability issues given the data we have seen from the use of ^{64}Cu SARTATE in NETs patients[1], and the prevention of copper leakage with Clarity's SAR technology (a known issue with copper isotopes contributing to side effects).

Efficacy data. A dose of 200MBq was determined as optimal and will be used in follow on Phase III trials (vs lower dose cohorts). **Figure 1** below summarises the accuracy data from the PROPELLER study for this 200 MBq cohort (n=18) (we averaged the 2 blinded readers to summarise) and that from the prospective proPSMA trial that was used as the primary Level 1 evidence to support the primary staging indication for both the ILLUCCIX and LOCAMETZ FDA approvals (reminder here).

Accuracy higher than SOC. Based on PROPELLER data there is a material improvement in accuracy (+12%) when comparing within subjects using the ^{64}Cu Dx versus the ^{68}Ga-PSMA-11 SOC (93% vs 81% respectively), noting however that the diagnostic performance of the ^{68}Ga SOC was lower in PROPELLER than in the proPSMA trial (~92%). We do call out however that the proPSMA study was not blinded for the reviewers, as opposed to PROPELLER where reviewers were blinded to which agent was used. The question as to this accuracy difference being material enough to shift clinician product choice is unclear, and needs further confirmation in later stage trials. The convenience aspects of a ^{64}Cu-based diagnostic are likely a greater driver of adoption in our view over incremental clinical accuracy improvements at the outset, however this may shift as the market matures and depends heavily on the delta (if any) that is confirmed in larger Phase III trials. In both cases Clarity have a compelling offering and data thus far.

Figure 1: Accuracy comparisons between new SOC (^{68}Ga-PSMA-11) and ^{64}Cu-SAR-bisPSMA from PROPELLER and proPSMA studies

Agent	^{64}Cu-SAR-bisPSMA	^{68}Ga-PSMA-11	^{68}Ga-PSMA-11
Trial ID	**PROPELLER**		**proPSMA**[2]
Actual enrolment	30 (incl. 18 in high dose cohort)		302 (150 per cohort)
Cohort	High-risk prostate cancer (pre-prostatectomy) PSA >10ng/ml for inclusion		High-risk prostate cancer (pre-prostatectomy) PSA >20ng/ml for inclusion
Design	Randomised. Patients acted as their own control & received both scans less than 5 weeks apart (>6 hours). Blinded review. Compared to histopathology as standard of truth.		Randomised, parallel design. Each patient only receiving one scan (either ^{68}Ga or SOC CT w bone scan) & results compared between cohorts. Compared to histopathology as standard of truth. Reviewers were not blinded to imaging modality.
Accuracy of detection Average (range)	92.9% (85.7-100%)	80.6% (77.8-83.3%)	92% (88-95%)

Source: Clarity Pharmaceuticals, Hofman et al (2020)[2].

[1] Hicks et al. (2019) ^{64}Cu-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.
[2] Hofman MS *et al.* (2020) Prostate-specific membrane antigen PET-CT in patients with high-risk prostate cancer before curative-intent surgery or radiotherapy (proPSMA): a prospective, randomised, multicentre study. *Lancet* 395(10231): 1208-1216.

Greater agent uptake into tumours. Once again, we have seen examples of 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. Further to this, one patient was reported to have secondary disease identified by ^{64}Cu-SAR-bisPSMA that was missed by the prior ^{68}Ga PSMA-11 scan conducted on the patient, which was confirmed as positive disease by pathology. This case provides an example of how clinical outcomes may be altered pending the accuracy of PSMA PET agents.

Where to from here? The positive results from PROPELLER provide a foundation for progression to a registrational Phase III trial campaign, with the support from future COBRA trial results. The COBRA study is also evaluating ^{64}Cu-SARbisPMSA however in biochemically recurrent (BCR) patients which represents the other key relevant patient population in prostate cancer for this diagnostic asset (akin to current marketed competitor products). COBRA results are expected in 3Q 2023 further de-risking this asset. As we have previously noted, we anticipate Clarity will adopt a pivotal trial design akin to that of Lantheus/Progenics' OSPREY trial in primary staging and pre-prostatectomy patients, with an approx. 16-month timeline taking market entry to early FY26e (assuming 2H CY23 trial start). This is anticipated to be in parallel to a Phase III in biochemical recurrence study (following on from COBRA) and we expect to be akin to Lantheus' CONDOR trial design.

A dual Phase III pipeline approach. 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.

Upcoming catalysts (CY23)

Three further readouts across 2023. As we have previously highlighted, there are three more key trial readouts from within Clarity's busy clinical development pipeline anticipated in 2023.

1. **Mid 2023 (2Q-3Q CY23e). CL04 Neuroblastoma Phase I/II trial topline data.** The most material catalyst is readout of Clarity's Neuroblastoma theranostic trial (CL04) anticipated in mid-2023 (could sit either side of the HY). This trial is evaluating both a diagnostic (Dx) agent and paired therapy (Tx) agent, and will include the first safety/efficacy readout for a ^{67}Cu-based therapeutic asset, as well as support a registrational Phase III follow on study/s (for Dx and Tx, separately). The materiality of this is greater than that of ^{64}Cu-based diagnostics, given they are a "proven" entity with respect to their being approved ^{64}Cu-based products on market (i.e. Curium's DetectNet). Efficacy of ^{67}Cu-SARTATE underpins the majority of value in Clarity's business, not at a specific product level, but from a proof-of-concept, demonstrating the clinical utility of ^{67}Cu-based therapies. Further validation of their value will be realised in Phase III (~late CY23e start), which will also demonstrate commercial manufacturing and availability challenges of the past have been resolved for ^{67}Cu with new electron accelerator production methods.

2. **2H 2023. COBRA Phase I/II trial topline data.** Using their same PSMA-diagnostic as PROPELLER, this trial provides data on utility in a second key prostate cancer patient population; those with biochemical recurrence (BCR). This study is conducted under IND in US sites, which we anticipate to be key follow on sites for a Phase III program with the ^{64}Cu-SAR-bisPSMA diagnostic program next year.

3. **2H 2023. DISCO Phase II data.** DISCO is Clarity's Phase II trial assessing the efficacy of ^{64}Cu SARTATE in Neuroendocrine Tumours (NETs), We see this as another important technology validating exercise particularly given this study aims to enrol ~63 participants, Clarity's largest trial to date. Whilst three PET imaging products exist in this indication (NETSPOT, DetectNet, DOTATATE), we see Clarity's ^{64}Cu SARTATE as a potential second generation product, with improved imaging properties (including over DetectNet - owing to copper leakage it experiences) and logistics.

Each trial readout represents material de-risking points in our valuation of Clarity, and advances clinical progression of their pipeline, particularly important with the transition to Phase II/III most attractive for M&A activity. As a reminder we anticipate first commercial revenues for Clarity from FY25e, noting that their PSMA prostate cancer program is the most material component of our risked valuation (47%).

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