

Copper takes a bigger chunk of the pie

We maintain our OVERWEIGHT rating on Clarity Pharmaceuticals and increase our risk PT to \$2.13/sh (unrisked \$5.15/sh). This upgrade is somewhat overdue, and has been percolating for some time, given all of the learnings we have amassed from watching the PSMA PET Dx market form and shift over the past 3 years. Clarity's strong share price performance is warranted and forces our hand to share the material market share lifts we now anticipate their ⁶⁴Cu-based Dx agents to take in prostate cancer PET/CT. Per our [sector note](#), we almost double our expectations for terminal TAM share of ⁶⁴Cu-SAR-bisPSMA (12% to 23%) and incorporate the non-PSMA avid asset, ⁶⁴Cu-SAR-BBN, into the broader PCa pie (total TAM US\$2.2B) - of which Clarity's Bombesin asset we believe comprises 13%. This is a clear consequence of not only more share (#scans) but also pricing premiums that we now appreciate CU6 will be able to derive, given the differentiation of their Dx agents (flexibility, convenience, clinical efficacy). 10-20% pricing premiums to current net ASPs of SOC PSMA agents (ILLUCCIX, PYLARIFY, POSLUMA) are justified in our minds for bisPSMA (10%) and more so for Bombesin (+20%) given its scarcity/lack of competitive tension in the non-PSMA avid PCa market. Of course, with Clarity we are not left absent de-risking catalysts for long, and eagerly look to SABRE topline data and further SECURE readouts in early CY24, as well as COBRA (bisPSMA in BCR indication) topline data as an early Christmas present.

Key points

Update pie gives a larger slice to CU6. We had pre-flagged that we anticipated market share upgrades for Clarity's ⁶⁴Cu bisPSMA Dx agent, given the conservative share we had initially forecast of just 12% of the mature TAM (now 23%). Two things have happened since our initial forecasting: 1) the TAM itself has grown substantially to what we may now foresee as a PSMA Dx market of 575k scans per year in US, vs 250K we initially modelled (owing to indication expansion); and 2) the formation of the PSMA Dx market and its current composition (4 agents thus far) has morphed with a duopoly (ILLUCCIX, PYLARIFY) that cannot compete with copper on the basis of dosing flexibility (1-24hr post imaging optionality), which looks to be driving increased ability to see metastatic lesions at the later time points. This should support share shifts particularly in the hospital settings, as well as modest pricing premiums (~10%). The prostate pie also includes non-PSMA avid patients now (~10% total), where Clarity's Bombesin agent looks to have the market to itself. In a combined sense, CU6's prostate Dx assets now surpass that of peers in a peak share sense once mature. See our [sector summary](#) for further detail.

Data readouts across the next 12 months (CY). 4Q23: COBRA topline data (BCR trial in PSMA avid PCa Dx). 1Q24: SABRE topline data (non-PSMA avid PCa Dx - which is a key de-risking point in model), SECURE Cohort 3 data (3+3 patients) including expanded access cohort updates; Phase II expansion in CL04 (Neuroblastoma diagnostic and therapy). 3Q24: BOP (non-PSMA avid PCa Dx) topline data; plus potential DISCO (NETs diagnostic) trial topline across CY24.

Forecasts & valuation. Maintain OVERWEIGHT. Lift of risk SOTP PT to \$2.13/sh (+38%) owing to pricing and market share upgrades (seen from FY26e) in the bisPSMA Dx and BBN Dx opportunities in PCa (material owing to the sheer size of these markets), moderated by a 50bps increase to RfR (now 4.0%). PT comprises: a) PSMA avid PCa \$1.42/sh; b) non-PSMA avid PCa \$0.53/sh; c) NB \$0.10/sh; and d) NETs \$0.08/sh. No value attributed to breast cancer. Unrisked PT \$5.15/sh.

Financial summary (Y/E Jun, AUD)	FY22A	FY23A	FY24E	FY25E	FY26E
Sales (\$m)	0.0	0.0	0.0	0.0	22.2
Consensus sales (\$m)			5.0	100.9	90.1
Sales growth (%)	n/m	n/m	n/m	n/m	n/m
EBITDA norm (\$m)	(23.8)	(26.3)	(35.9)	(51.4)	(60.0)
EV/EBITDA (x)	n/m	n/m	n/m	n/m	n/m

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

Wilsons Equity Research

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Recommendation	OVERWEIGHT
12-mth target price (AUD)	\$2.13
Share price @ 6-Dec-23 (AUD)	\$1.43
Forecast 12-mth capital return	49.0%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	49.0%

Market cap (\$m)	374.5
Enterprise value (\$m)	309.4
Shares on issue (m)	261.9
Sold short (%)	0.0
ASX All Ords weight (%)	0.0
Median turnover/day (\$m)	0.3

Dr Melissa Benson

melissa.benson@wilsonsadvisory.com.au
Tel. +61 2 8247 6639

Dr Shane Storey

shane.storey@wilsonsadvisory.com.au
Tel. +61 7 3212 1351

Madeleine Williams

madeleine.williams@wilsonsadvisory.com.au
Tel. +61 3 9640 3834

12-mth price performance (\$)



	1-mth	6-mth	12-mth
Abs return (%)	26.5	90.7	49.7
Rel return (%)	25.2	92.0	54.2

Key changes	30-Aug	After	Var %
Sales FY24E	0.0	0.0	0%
(\$m) FY25E	0.0	0.0	0%
FY26E	13.4	22.2	66%
EBITDA FY24E	(35.9)	(35.9)	0%
norm FY25E	(51.4)	(51.4)	0%
(\$m) FY26E	(67.0)	(60.0)	10%
Price target	1.55	2.13	38%
Rating	O/W	O/W	

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) positive clinical data readouts; b) achievement of trial endpoints; c) partnership opportunities; d) regulatory approvals.

Investment Thesis

Maintain our OVERWEIGHT rating on Clarity Pharmaceuticals and increase our risk PT to \$2.13/sh. This upgrade has been percolating for some time given all of the learnings we have amassed from watching the PSMA PET Dx market form and shift over the past 2 years. We almost double our expectations for terminal TAM share of ⁶⁴Cu-SAR-bisPSMA and now appreciate CU6 will be able to derive given the differentiation of their Dx agents (flexibility, convenience, clinical efficacy).

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)	FY22A	FY23A	FY24E	FY25E	FY26E
Sales	0.0	0.0	0.0	0.0	22.2
EBITDA norm	(23.8)	(26.3)	(35.9)	(51.4)	(60.0)
EBIT norm	(23.8)	(26.4)	(36.0)	(51.5)	(60.1)
PBT norm	(23.7)	(24.5)	(35.7)	(51.3)	(59.9)
NPAT norm	(23.8)	(24.6)	(35.7)	(51.3)	(61.6)
NPAT reported	(23.8)	(24.6)	(35.7)	(51.3)	(61.6)
EPS norm (cents)	(9.8)	(9.5)	(13.8)	(17.4)	(16.8)
DPS (cents)	0.0	0.0	0.0	0.0	0.0

Growth (%)	FY22A	FY23A	FY24E	FY25E	FY26E
Sales	n/m	n/m	n/m	n/m	n/m
EBITDA norm	132.8	10.4	36.6	43.3	16.7
NPAT norm	133.2	3.6	45.3	43.6	20.0
EPS norm (cents)	69.3	(2.8)	45.3	26.0	(3.6)
DPS (cents)	n/m	n/m	n/m	n/m	n/m

Margins and returns (%)	FY22A	FY23A	FY24E	FY25E	FY26E
EBITDA margin	n/m	n/m	n/m	n/m	(270.5)
EBIT margin	n/m	n/m	n/m	n/m	(271.1)
PBT margin	n/m	n/m	n/m	n/m	(270.1)
NPAT margin	n/m	n/m	n/m	n/m	(277.7)

Interims (\$m)	2H22A	1H23A	2H23A	1H24E	2H24E
Sales	0.0	0.0	0.0	0.0	0.0
EBITDA norm	(10.1)	(11.8)	(14.5)	(15.4)	(20.5)
EBIT norm	(10.1)	(11.8)	(14.5)	(15.5)	(20.5)
PBT norm	(10.0)	(11.2)	(13.3)	(15.3)	(20.4)
NPAT norm	(10.0)	(11.2)	(13.4)	(15.3)	(20.4)
NPAT reported	(10.0)	(11.2)	(13.4)	(15.3)	(20.4)
EPS norm (cents)	(4.0)	(4.3)	(5.2)	(5.9)	(7.9)
DPS (cents)	0.0	0.0	0.0	0.0	0.0

Stock specific	FY22A	FY23A	FY24E	FY25E	FY26E
R&D expenditure (\$m)	(18.9)	(31.5)	(39.3)	(40.5)	(57.7)
bisPSMA Dx sales (\$m)			0.0	0.0	19.6
Bombesin Dx sales (\$m)			0.0	0.0	2.6

Source: Company data, Wilsons estimate, Refinitiv, IRESS.
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Balance sheet (\$m)	FY22A	FY23A	FY24E	FY25E	FY26E
Cash & equivalents	92.3	65.0	32.1	27.6	59.3
Current receivables	6.7	10.0	5.0	5.0	7.3
Current inventory	0.0	0.0	0.0	0.0	0.4
PPE	0.3	0.2	0.2	0.1	0.1
Total assets	99.8	76.9	38.9	34.3	68.8
Current payables	6.8	6.7	4.0	4.9	7.1
Total debt	0.0	0.0	0.0	0.0	0.0
Total liabilities	7.6	7.7	4.7	6.1	8.3
Shareholders equity	92.2	69.2	34.2	28.2	60.5

Cash flow (\$m)	FY22A	FY23A	FY24E	FY25E	FY26E
Operating cash flow	(13.3)	(27.5)	(32.9)	(51.4)	(62.2)
Maintenance capex	(0.2)	(0.0)	(0.1)	(0.1)	(0.1)
Free cash flow	(13.5)	(27.5)	(33.0)	(51.5)	(62.2)
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	(32.1)	3.2	33.8	0.0	0.0
Cash flow pre-financing	(45.6)	(24.3)	0.8	(51.5)	(62.2)
Funded by equity	92.1	0.0	0.0	47.0	94.0
Funded by cash/debt	(139.0)	24.1	(0.8)	(42.5)	(125.8)

Liquidity	FY22A	FY23A	FY24E	FY25E	FY26E
Cash conversion (%)	56.2	110.3	92.4	100.4	101.2
Net debt (\$m)	(92.3)	(65.0)	(32.1)	(27.6)	(59.3)
Net debt / EBITDA (x)	3.9	2.5	0.9	0.5	1.0
ND / ND + Equity (%)	n/m	n/m	n/m	n/m	n/m
EBIT / Interest expense (x)	n/m	14.1	n/m	n/m	n/m

Valuation	FY22A	FY23A	FY24E	FY25E	FY26E
EV / Sales (x)	n/m	n/m	n/m	n/m	14.2
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)	3.8	5.4	10.8	19.1	8.9
FCF yield (%)	(3.8)	(7.4)	(8.9)	(9.5)	(11.5)
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)	243.1	259.0	259.0	295.2	367.5

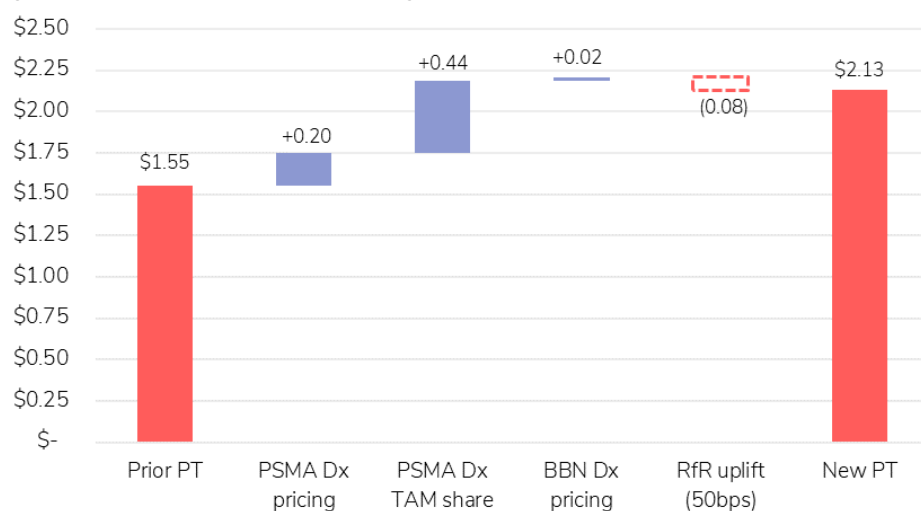
Valuation uplift: components

38% lift in PT driven primarily by market share upgrades for ⁶⁴Cu-SAR-bisPSMA Dx

Our material valuation uplift in risked PT comprises: a) market share increases in PCa ⁶⁴Cu-SAR-bisPSMA Dx agent from 12% to 23% of our updated PCa Dx pie ([sector note](#)) in the mature US market; b) pricing uplifts for ⁶⁴Cu-SAR-bisPSMA Dx from net US\$2,700 per dose to US\$4,200 per dose; c) pricing uplifts for ⁶⁴Cu-SAR-BBN Dx in non-PSMA avid PCa from US\$3,690 per dose to US\$4,900 per dose; and d) risk free rate elevation by 50bps to 4.0% we are rolling through our healthcare coverage. **Figure 1** demonstrates the contribution of each of these pieces in forming our new \$2.13/sh risked PT for Clarity Pharmaceuticals.

Note that only the US market models have been upgraded (pricing, share) with no changes made to our EU market models, and our previous net pricing for the PCa Dx agents were conservative/below current SOC pricing and so this upgrade represents a lift to SOC as well as building in a sustained slight (10%) premium to SOC in this market across its launch. Our ⁶⁴Cu-SAR-BBN pricing uplift sets new net pricing at ~20% premium to PSMA PET/CT agents (PYLARIFY, ILLUCCIX, POSLUMA) noting the scarcity principle that will be associated with Clarity's Bombesin (BBN) diagnostic offering in non-PSMA avid prostate cancer.

Figure 1: The components of our 38% upgrade in risked PT from \$1.55 to \$2.13 per share



Source: Wilsons estimates.

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Wilsons contact

For more information please phone: 1300 655 015 or email: publications@wilsonsadvisory.com.au