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**Theme** Company Update Sector

Healthcare

## Company

# BEAM ON in Wisconsin

We maintain our OVERWEIGHT rating on Clarity Pharmaceuticals and risked price target of \$1.22/sh. The company's <sup>67</sup>Cu manufacturing partner (NorthStar Medical Isotopes; NSMI) held a site tour last week in Wisconsin. We attended to validate progress and to discuss matters of purification, yield, supply chain and regulatory pathways. <sup>67</sup>Cu has been the rate limiting step preventing the broad translation of the <sup>64/67</sup>Cu 'perfect theranostic pair' for theranostic development. Whilst volumes are modest and there is COGS optimisation to come, NSMI's reduction to practice of photonuclear production using electron accelerators is a major milestone. The arrival of <sup>67</sup>Cu as commercial (rather than research) isotope increases the value of Clarity's sarcophogene (SAR) conjugation chemistry.

## Key points

The physics of <sup>67</sup>Cu production now an engineering reality. Based in Beloit (Wisconsin), NSMI has built an impressive capability to produce <sup>99</sup>Mo, <sup>67</sup>Cu and <sup>225</sup>Ac. We understand that approximately US\$120M has been invested to date, with a third, <sup>225</sup>Ac-dedicated module nearing completion. NSMI has recently broken ground on an adjoining property, allowing expansion to at least eight electron accelerators (Rhodotrons), enough to service the US market. In the case of <sup>67</sup>Cu, the engineering challenge of performing a novel, photonuclear reaction at scale is now validated. Briefly, the rhodotrons accelerate electrons to produce and direct high energy gamma rays, bombarding a solid, highly purified (98.97%) <sup>68</sup>Zn target. The rhodotrons supplied by Belgian manufacturer IBA are thus 'Beam On' and producing. The <sup>67</sup>Cu is recovered by dissolving irradiated targets in hydrochloric acid and using chromatographic (chelation) techniques to achieve high radiochemical yields. Production scale is modest and challenges remain from a COGS perspective. Highly purified <sup>68</sup>Zn targets are expensive but are available from several providers. <sup>68</sup>Zn pricing is expected to fall as demand increases with the desire for cyclotron-produced <sup>68</sup>Ga being another reason to scale up global supply. Our conversations with targetry suppliers at SNMMI confirmed as much. NSMI is working to optimise its on-site processes for capturing and recycling un-converted <sup>68</sup>Zn material. Interestingly, the reclaimed <sup>68</sup>Zn targets that NSMI prepares on-site increase in purity over time because trace impurities (metals) are stripped out over successive separation runs.

SECuRE radioligand therapy (RLT) progress abuzz. Investigators involved with Clarity's <sup>67</sup>Cu SAR-bisPSMA program brought unique perspectives, with years of clinical trial (VISION, PSMAfore, PSMAddition Phase IIIs) and real-world PLUVICTO therapy experience under their belts. There is a consensus view that PLUVICTO's ability to drop PSA levels sharply and profoundly (by at least 50% if not 75%) correlates with survival outcomes and argues strongly for the earlier deployment of RLT in prostate cancer. Having witnessed deep responses to Clarity's 4GBq dose, PIs are excited to see what comes from dosing at 8GBq and 12GBq over coming months, noting, PLUVICTO is dosed at 7.4GBq. Theoretically, Clarity's PIs are pointing to the agent's 2-3x tumour uptake and longer half-life as key differentiating features.

**Forecasts & valuation.** Changes reflect post 1H23 model maintenance only. Risked SOTP valuation of \$1.22/sh comprises a) prostate \$1.01/sh; b) Neuroblastoma \$0.11/sh; and c) NETs \$0.10/sh. No value currently attributed to breast cancer. Unrisked PT \$4.45/sh. Positive clinical readouts over next 6-9 months de-risk valuation by 15% to \$1.40/sh.

Financial summary (Y/E Jun, AUD)	FY21A	FY22A	FY23E	FY24E	FY25E
EBITDA norm (\$m)	(10.2)	(23.8)	(22.6)	(26.5)	(44.9)
Consensus EBITDA (\$m)			(28.0)	(34.9)	90.6
EPS norm (cents)	(5.8)	(9.8)	(8.5)	(10.2)	(14.1)
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.

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# Clarity Pharmaceuticals (CU6)

Recommendation	OVERWEIGHT
12-mth target price (AUD)	\$1.22
Share price @ 3-Jul-23 (AUD)	\$0.73
Forecast 12-mth capital return	67.1%
Forecast 12-mth dividend yield	0.0%
12-mth total shareholder return	67.1%
Market cap (\$m)	189.3
Enterprise value (\$m)	96.9
Shares on issue (m)	259.3
Sold short (%)	0.0
ASX All Ords weight (%)	0.0
Median turnover/day (\$m)	0.2

#### Dr Melissa Benson

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

#### **Dr Shane Storey**

<u>shane.storey@wilsonsadvisory.com.au</u> Tel. +61 7 3212 1351

#### Madeleine Williams

<u>madeleine.williams@wilsonsadvisory.com.au</u> Tel. +61 3 9640 3834

#### 12-mth price performance (\$)



	1-mth	6-mth	12-mth
Abs return (%)	(0.7)	(26.5)	46.9
Rel return (%)	(1.4)	(27.7)	38.4

Key changes	5	14-Feb	After	Var %
EBITDA	FY23E	(23.9)	(22.6)	5%
norm	FY24E	(26.5)	(26.5)	0%
(\$m)	FY25E	(44.9)	(44.9)	0%
EPS	FY23E	(9.9)	(8.5)	14%
norm	FY24E	(11.0)	(10.2)	8%
(cents)	FY25E	(15.1)	(14.1)	6%
Price target		1.22	1.22	-0%
Rating		O/W	O/W	

### Business Description

Clarity is a clinical stage radiopharmaceutical company developing nextgeneration 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.

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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)	(22.6)	(26.5)	(44.9)
EBIT norm	(10.2)	(23.8)	(22.7)	(26.6)	(45.0)
PBT norm	(10.2)	(23.7)	(21.9)	(26.4)	(44.7)
NPAT norm	(10.2)	(23.8)	(22.0)	(26.4)	(44.7)
NPAT reported	(10.4)	(23.8)	(22.0)	(26.4)	(44.7)
EPS norm (cents)	(5.8)	(9.8)	(8.5)	(10.2)	(14.1)
DPS (cents)	0.0	0.0	0.0	0.0	0.0
Grouth (04)	EV21 A	EV22A	EV22E	EV24E	EVOEE

Growth (%)	FY21A	FY22A	FY23E	FY24E	FY25E
Sales	n/m	n/m	n/m	n/m	n/m
EBITDA norm	45.5	132.8	(4.9)	17.2	69.2
NPAT norm	45.9	133.2	(7.5)	20.0	69.5
EPS norm (cents)	(80.2)	69.3	(13.2)	20.0	38.6
DPS (cents)	n/m	n/m	n/m	n/m	n/m

Margins and returns (%)	FY21A	FY22A	FY23E	FY24E	FY25E
Interims (\$m)	1H22A	2H22A	1H23A	2H23E	1H24E
Sales	0.0	0.0	0.0	0.0	0.0
EBITDA norm	(13.7)	(10.1)	(11.8)	(10.8)	(11.1)
EBIT norm	(13.7)	(10.1)	(11.8)	(10.9)	(11.1)
PBT norm	(13.7)	(10.0)	(11.2)	(10.7)	(11.0)
NPAT norm	(13.7)	(10.0)	(11.2)	(10.7)	(11.0)
NPAT reported	(13.7)	(10.0)	(11.2)	(10.7)	(11.0)
EPS norm (cents)	(5.8)	(4.0)	(4.3)	(4.1)	(4.2)
DPS (cents)	0.0	0.0	0.0	0.0	0.0
Stock specific	FY21A	FY22A	FY23E	FY24E	FY25E
R&D expenditure (\$m)	(9.7)	(18.9)	(26.7)	(28.8)	(32.6)

### Investment Thesis

Maintain OW and risked PT of \$1.22/sh. Clarity's <sup>67</sup>Cu manufacturing partner NSMI held a site tour last week in Wisconsin. We attended to validate progress. <sup>67</sup>Cu has been the rate limiting step preventing the broad translation of the <sup>64/67</sup>Cu 'perfect theranostic pairing'. NSMI's reduction to practice of photonuclear production on electron accelerators is a key milestone. The arrival of <sup>67</sup>Cu as commercial isotope increases the value of CU6's SAR conjugation chemistry.

## Risks

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

Balance sheet (\$m)	FY21A	FY22A	FY23E	FY24E	FY25E
Cash & equivalents	18.9	92.3	68.8	42.8	73.3
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	0.2	0.1	0.1
Total assets	22.6	99.8	74.6	48.5	79.0
Current payables	1.8	6.8	2.4	3.1	4.4
Total debt	0.0	0.0	0.0	0.0	0.0
Total liabilities	2.3	7.6	2.7	3.7	5.6
Shareholders equity	20.3	92.2	71.9	44.7	73.4
Cash flow (\$m)	FY21A	FY22A	FY23E	FY24E	FY25E
Operating cash flow	(7.7)	(13.3)	(23.6)	(26.0)	(44.6)
Maintenance capex	(0.1)	(0.2)	(0.0)	(0.0)	(0.0)
Free cash flow	(7.7)	(13.5)	(23.6)	(26.1)	(44.6)
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)	31.0	5.0	0.0
Cash flow pre-financing	(8.4)	(45.6)	7.4	(21.1)	(44.6)
Funded by equity	20.9	92.1	0.0	0.0	75.2
Funded by cash/debt	(24.0)	(139.0)	4.5	26.1	(105.8)
Liquidity	FY21A	FY22A	FY23E	FY24E	FY25E
Cash conversion (%)	75.6	56.2	106.6	99.1	100.0
Net debt (\$m)	(18.9)	(92.3)	(68.8)	(42.8)	(73.3)
Net debt / EBITDA (x)	1.9	3.9	3.0	1.6	1.6
ND / ND + Equity (%)	n/m	n/m	n/m	n/m	n/m
EBIT / Interest expense (x)	n/m	n/m	28.4	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)	6.3	1.9	2.6	4.2	3.4
FCF yield (%)	(6.1)	(7.6)	(12.7)	(14.0)	(17.8)
Dividend yield (%)	0.0	0.0	0.0	0.0	0.0
D	0.0	0.0	0.0	0.0	0.0
Payout ratio (%)	0.0	0.0	0.0	0.0	0.0

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



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### | Wilsons contact

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