BELL POTTER

Speculative

See key risks on Page 4 and Biotechnology Risk Warning on Page 7. Speculative securities may not be suitable for Retail Clients.

2 May 2024

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Clarity Pharma (CU6)

Mandate To Complete Approval Studies

Recommendation
Buy (unchanged)
Price
$3.01
Valuation
$4.00 (previously $3.90)
Risk
Speculative

Sector

Pharmaceuticals & Biotechnology

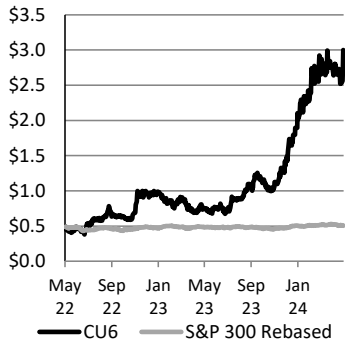
Expected Return	
Capital growth	**32.9%**
Dividend yield	**0.0%**
Total expected return	**32.9%**

Company Data & Ratios	
Enterprise value	**$795.4m**
Market cap	**$935.4m**
Issued capital	**310.8m**
Free float	**89%**
Avg. daily val. (52wk)	**$750k**
12 month price range	**$0.67 - $3.05**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	2.75	2.29	0.75
Absolute (%)	9.09	30.84	301.24
Rel market (%)	13.21	30.45	297.40

Absolute Price



SOURCE: IRESS

First Complete Response

^{67}Cu SAR-bis-PSMA has achieved its first complete response in a late stage prostate cancer patient. One patient in the SECuRE trial has been reclassified as a complete responder (CR) according the RECIST criteria. i.e. no detectable lesion in the April 2024 CT Scan. In addition, there was no PSMA uptake in any lesion using ^{64}CU-SAR-bisPSMA. The patient had received 2 doses of drug at 8GBq/dose – being one of the interim doses.

Achieving a complete response is one thing, sustaining that response for >6 months is next level. The complete responder discussed here appears to have been cancer free for at least 6 months. This patient had failed on multiple lines of previous therapy and ordinarily would have been subject to palliative care or perhaps Pluvicto.

The SECuRE trial is ongoing and is currently dosing cohort 4, being up to 4 doses of ^{67}Cu SAR-bisPSMA at 12GBq/dose. Being a dose escalation study, recruitment takes time as patients are monitored closely for toxicity as each dose is administered. In addition, the period between doses may be up to 6-8 weeks. Assuming there are no toxicity issues, cohort 4 will be followed by a dose expansion cohort in up to 14 patients at the same dose (i.e. 4x12BGq). We expect a readout on the expansion study towards the end of the calendar year or 1Q CY25.

Investment View: Retain Buy (Spec.), Valuation $4.00

The announcement of the first CR is overwhelmingly positive news. Retain Buy (Speculative) rating, valuation raised to $4.00. Adjustments to earnings include upward revisions to FY25 R&D expense. The model had previously allowed for dilution from a capital raise. Shares on issue increase by 18% following the recent transaction to raise $121m @ $2.55. Following this transaction and receipt of the FY23 R&D Tax refund ($10.1m), we estimate cash at 30 April 2024 of ~$150m. CU6 has 7 clinical trials in progress with the priorities being CLARIFY (diagnostic imaging) and SECuRE – as discussed here. Next catalyst include further interim data from SECuRE.

Earnings Forecast

June Year End	FY23	FY24e	FY25e	FY26e
Revenues $m	0.0	0.0	0.0	97.1
EBITDA $m	-26.4	-42.7	-59.5	4.5
NPAT (underlying) $m	-24.6	-42.7	-59.5	4.5
NPAT (reported) $m	-24.6	-42.7	-59.5	4.5
EPS underlying (cps)	-9.6	-13.7	-19.1	1.4
EPS growth %	na	na	na	na
PER (x)	nm	nm	nm	207.9
FCF yield (%)	0%	0%	0%	0%
EV/EBITDA (x)	nm	nm	nm	207.9
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0%	0%	0%	0%
ROE %	na	na	na	5%

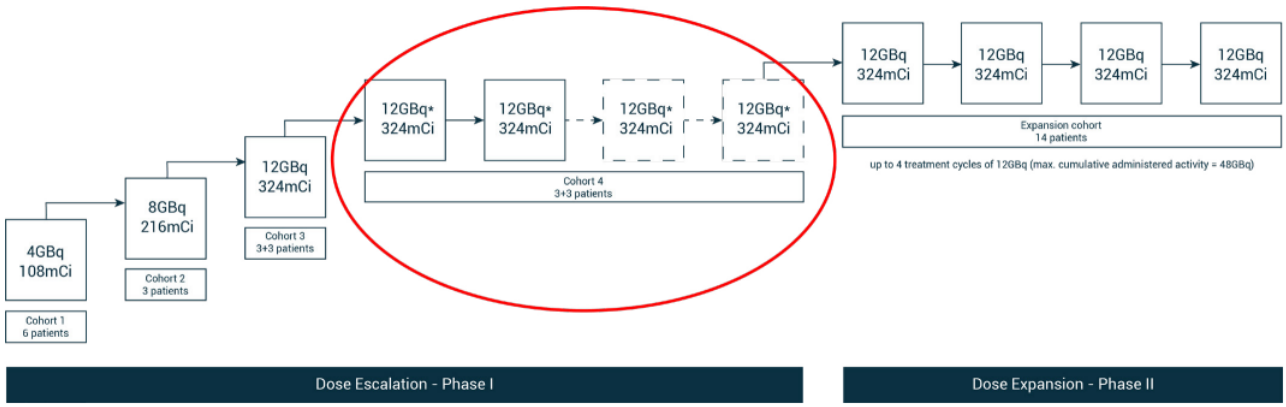
SOURCE: BELL POTTER SECURITIES ESTIMATES

Therapeutic trial progressing nicely

What to expect from here

Figure 1 is the summary trial design for SECuRE.

Figure 1 - SECuRE clinical trial design overview



SOURCE: COMPANY DATA

Key features:

Single arm (i.e. no randomisation or control) in patients with metastatic castrate resistant prostate cancer. All patients have progressed on multiple lines of therapy including ARPI's and chemotherapy but not Pluvicto.

Endpoints – safety and tolerability, determination of final dose for subsequent studies.

The complete responder came from cohort 2 who received a first dose of 67Cu-SAR bisPSMA within the trial, followed by a second dose as part of the expanded access program available only to trial participants.

Enrolment in the trial is continuing in cohort 4 (circled area in figure 1). Subject to ongoing monitoring for toxicity, the trial is expected to conclude later this year with the enrolment of an expansion cohort of ~14 patients dosed at 4 x 12GBq. The company will continue to monitor all patients for efficacy measures (progression free survival, duration of response and overall survival) and safety well after the final dose. Interim readouts are expected to continue for many months before a final readout in 2025.

The target market for a phase III trial is likely to remain salvage patients. We estimate the TAM at 40K patient per year in the US alone. Assuming 50% of these men seek treatment, the market value is ~US$5bn.

BENCHMARK FOR COMPLETE RESPONSE

For comparison purposes, the phase III VISION study (responsible for the approval of Pluvicto) yielded a complete response rate of 9.2% (17 of 184 patients). Pluvicto is the only approved radiopharmaceutical for the treatment of metastatic prostate cancer. The same trial produced progression free survival of 8.7 months vs 3.4 months for the control group.

By the end of the SECuRE trial, up to 32 patients will have been treated with up to 20 patients on the target final dose (4x12BGq). The efficacy data which eventually emerges in FY25 should provide a meaningful indication of effect size and will also be instructive for determination of patient numbers in an approval study. The nature of the subsequent studies (i.e. randomised phase II or phase III) will be a key decision for consideration by

the Board and its advisors in CY25. We do not expect an approval study to commence before CY26, however, it is likely the next trial will be targeted to approval.

Pluvicto is on a run rate for revenues in CY2024 in excess of US$1bn. The supply of the drug to the US market has been a major limiting factor for Novartis due to the limited supply of ^{177}Lu.

Clarity will face no such problem with the supply of ^{67}Cu if the drug is eventually approved, having recently signed an exclusive supply agreement with Northstar for the production of drug product for clinical trials. It not unreasonable to assume this arrangement would be extended to the supply of commercial quantities following approval. The Northstar facility produces ^{67}Cu on linear accelerators at its facility in Wisconsin US, for distribution across the United States.

Figure 1 - Summary earnings changes

	2024			2025			2026		
	New	Old	% change	New	Old	% change	New	Old	% change
Revenues	0.0	0.0	na	0.0	0.0	na	97.1	97.1	0%
EBIT	-42.7	-41.2	-4%	-59.5	-49.5	20%	4.5	14.5	-69%
NPAT	-42.7	-41.2	-4%	-59.5	-49.5	20%	4.5	14.5	-69%
EPS	-13.7	-16.1	15%	-19.1	-16.7	15%	1.4	4.9	-70%

SOURCE: BELL POTTER SECURITIES ESTIMATES

The FY25 loss increases by ~$10m following adjustment to the expected R&D spend. The FY26 R&D spend has also increased. By late CY25 we expect to have far greater precision on timing of the approval study(s) for 67Cu-SAR-bisPSMA.

The recent capital raise has resulted in the issue of ~47m shares or 18% of the previous shares on issue.

Next catalysts include ongoing interim data from SECuRE and numerous other trials covering SARTATE and BOMBESIN.

Following these adjustments and further revisions to revenue assumptions beyond FY26, our valuation is increased to $4.00 (from $3.90). We maintain our Buy (Speculative) rating.

Clarity Pharmaceuticals

Clarity Pharmaceuticals specialises in the development of Targeted Copper Theranostics (TCT) for the imaging and treatment of selected cancers. Radiopharmaceuticals are a well established field of medicine and in recent years it has experienced significant expansion thanks to the development of new technology. In particular the identification of certain cancer biomarkers and new science to target those biomarkers with either small molecules or monoclonal antibodies attached to a rapidly decaying isotope has facilitated

The company has an extensive program of clinical development for imaging and cancer therapy with a series of important data readouts over the next few years.

CU6 has an extensive register of patents including 17 patent families covering its intellectual property.

Key Risk include (but are not limited to):

Clinical Risk: CU6's clinical assets have shown promising results to date. However, there is no guarantee that the current or future pipeline assets will show sufficient safety and efficacy to drive approval in ongoing clinical trials. We also note clinical trial delays may be attributable to difficulty in recruiting, especially in markets with an existing diagnostic and therapeutic options which could exclude patients from the trial and could cause actual timelines and results to differ from forecasts.

Regulatory Risk: Failure to achieve regulatory approval, or other regulatory progress (including favourable trial design, or breakthrough designation) adds an element of risk.

Reimbursement Risk: Successful and reasonable levels of reimbursement will be key for Clarity's products to see market uptake. Reimbursement will depend on the clinical impact of the pipeline assets, and their ability to create clinically meaningful impacts, across both diagnostic and therapeutics. We have incorporated pricing in line with peers within our forecasts, but failure to secure reimbursement at those levels could cause results to differ from our product.

Commercial Risk: Our forecasts rely on neuroblastoma, prostate cancer, and neuroendocrine imaging to remain commercially attractive markets, and that Clarity will achieve solid market share within those markets, in the long run. However, certain targets exist in already crowded therapeutic areas, with existing clinical solutions, and in some cases with existing radiopharmaceutical solutions. Clarity will be required to show data in line, or improved to, those available therapies, especially as a later entrant onto those markets.

Going Concern: Our forecasts include an assumption of future cash inflows from the sale of Rare Paediatric Disease Vouchers in 2027 followed by commercial revenues from various assets in development. There are numerous milestones to be achieved in order to realise these cash future inflows. In the event that these milestones are not achieved, the company may require further cash from shareholders to support its activities.

Intellectual property risk: Clarity's ability to maintain a competitive advantage with its proprietary products rely on the existing and future patent portfolio. The failure of current patents, or future patents, to protect the company's proprietary portfolio, or infringement of the company's intellectual property, could result in additional costs or cause actual results to differ from financial results.

Clarity Pharma
as at 2 May 2024

Recommendation	Buy, Speculative
Price	$3.01
Valuation	$4.00

Table 2 - Financial summary

A$m	FY22	FY23	FY24e	FY25e	FY26e
Year Ending 30 June					
Total Revenue	**-**	**-**	**-**	**-**	**97.1**
COGS	-	-	-	-	(29.1)
Gross profit	-	-	-	-	68.0
Administration and coporate costs	-4.6	-4.7	-8.0	-10.0	-12.0
R&D costs	-18.9	-31.5	-45.2	-60.0	-60.0
Share based payments	0.0	0.0	-1.5	-1.5	-1.5
Other income and expenses	6.5	9.8	12.0	12.0	10.0
Total Expenses	-17.0	-26.4	-42.7	-59.5	-63.5
EBITDA	-17.0	-26.4	-42.7	-59.5	4.5
Depreciation & Amortisation	0.0	0.0	0.0	0.0	0.0
EBIT	-17.0	-26.4	-42.7	-59.5	4.5
Interest income/(expense)	0.0	1.9	0.0	0.0	0.0
Pre tax profit	(17.0)	(24.5)	(42.7)	(59.5)	4.5
Tax benefit	0.0	-0.1	0.0	0.0	0.0
Adjusted NPAT	-17.0	-24.6	-42.7	-59.5	4.5
Options expense - CGF	(6.8)	-	-	-	-
NPAT Reported	(23.8)	(24.6)	(42.7)	(59.5)	4.5

Cashflow (A$m)	FY22	FY23	FY24e	FY25e	FY26e
EBITDA	-17.0	-26.4	-42.7	-59.5	4.5
Add back: Share based payments	0.0	0.0	1.5	1.5	1.5
Working capital movement	3.7	-2.6	1.4	-1.6	-3.7
Other	0.0	0.0	0.0	0.0	0.0
Operating cash flow	-13.3	-27.5	-39.8	-59.6	2.3
Payment for PPE	-0.2	0.0	0.0	0.0	0.0
Free cash flow	-13.5	-27.5	-39.8	-59.6	2.3
Proceeds from issuance	86.9	0.2	118.1	0.0	0.0
Movement in borrowings	0.0	0.0	0.0	0.0	0.0
Dividends paid	0.0	0.0	0.0	0.0	0.0
Change in cash held	73.4	-27.2	78.3	-59.6	2.3
Cash at beginning of period	19.0	92.4	65.0	143.3	83.7
FX adjustment	0.0	-0.1	0.0	0.0	0.0
Cash at year end	92.4	65.0	143.3	83.7	85.9

Balance Sheet (A$m)	FY22	FY23	FY24e	FY25e	FY26e
Cash and short term investments	92.4	65.0	143.3	83.7	85.9
Other current assets	7.1	11.7	11.7	15.2	19.7
Property, Plant and Equipment	0.3	0.2	0.2	0.2	0.2
Total assets	99.8	76.9	155.2	99.1	105.9
Trade payables	6.8	6.7	7.0	8.0	8.0
Other liabilities	-	-	-	-	-
Provisions	0.8	1.0	2.1	3.0	4.0
Total Liabilities	7.6	7.7	9.1	11.0	12.0
Net Assets	92.2	69.1	146.1	88.1	93.9
Share capital	132.1	132.8	250.9	250.9	250.9
Reserves	5.9	6.7	8.2	9.7	11.0
Accumulated losses	(45.8)	(70.4)	(113.0)	(172.5)	(168.0)
Shareholders Equity	92.2	69.1	146.1	88.1	93.9

Valuation Ratios (A$m)	FY22	FY23	FY24e	FY25e	FY26e
Reported EPS (cps)	-6.6	-9.6	-13.7	-19.1	1.4
Normalised EPS (cps)	-6.6	-9.6	-13.7	-19.1	1.4
EPS growth (%)	na	na	na	na	na
PE(x)	**nm**	**nm**	**nm**	**nm**	**207.9**
EV/EBIT (x)	-46.8	-30.2	-18.6	-13.4	176.8
P/NTA (x)	8.4	11.2	6.4	10.6	10.0
Book Value Per Share (cps)	36	27	47	28	30
Price/Book (x)	8.4	11.2	6.4	10.6	10.0
DPS (cps)	-	-	-	-	-
Payout ratio %	0%	0%	0%	0%	0%
Dividend Yield %	0%	0%	0%	0%	0%
Franking %	0%	0%	0%	0%	0%
FCF yield %	0%	0%	0%	0%	0%
Net debt/Equity	0%	0%	0%	0%	0%
Net debt/Assets	net cash	net cash	net cash	net cash	net cash
Gearing	0%	0%	0%	0%	0%
Net debt/EBITDA (x)	n/a	n/a	n/a	n/a	n/a
Interest cover (x)	-	-	-	-	-

Revenue Analysis	FY22	FY23	FY24e	FY25e	FY26e
SAR-bis PSMA Prostate Cancer					
64Cu SARTATE NET diagnostic	-	-	-	-	1
Imaging PSMA +ve lymph nodes	-	-	-	-	96
	-	-	-	-	97

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

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