BELL POTTER

10 October 2023

Speculative
See key risks on Page 7 & 8 and Biotechnology Risk Warning on Page 11. Speculative securities may not be suitable for Retail Clients.

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Paradigm Biopharmaceuticals (PAR)

iPPS Provides OA Pain Relief At 1 Year

Recommendation
Buy (unchanged)
Price
$0.60
Valuation
$1.40 (previously $2.20)
Risk
Speculative

GICS Sector
Pharmaceuticals & Biotechnology

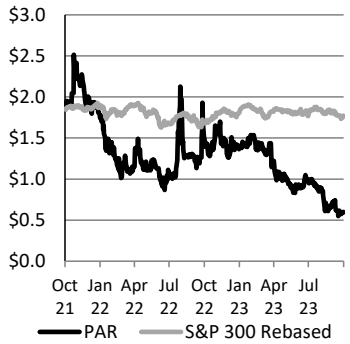
Expected Return	
Capital growth	133.3%
Dividend yield	0.0%
Total expected return	133.3%

Company Data & Ratios	
Enterprise value	$112.3m
Market cap	$168.3m
Issued capital	280.4m
Free float	$92%
Avg. daily val. (52wk)	$702,000
12 month price range	$0.53 - $1.73

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	0.65	1.01	1.62
Absolute (%)	-7.69	-40.59	-62.85
Rel market (%)	-4.63	-37.52	-65.66

Absolute Price



SOURCE: IRESS

Durability Of Pain Relief Out To 12 Months

PAR reported 12 month efficacy data from PARA_OA_008 earlier today. This study was designed to analyse the durable effect of iPPS on OA pain and function in addition to exploring the disease modify characteristics of the drug via a biomarker analysis. Patients on the highest dose continued to show significant reductions in pain along with improvements in function 12 months after dosing. In addition, patients on drug showed a 5x reduction in use of rescue medication and material improvements in global impression of change. The results are highly supportive of development.

Dosing Study Rules Out Lower Dose

Enrolment of stage one – the dose finding study of the phase 3 PARA_OA_002 is complete. Interim analysis has confirmed that neither of the lower dose regimens demonstrated a material difference in efficacy vs placebo which was not a surprise (to us at least). The company will now focus the OA program on the 6 week, twice weekly 2mg/kg dose regimen and this will require an amendment to the proposed phase 3 protocol. PAR believes it has the appropriate clinical and pre-clinical data to support this change. Hundreds of patients have been dosed with iPPS at this higher dose in Australia with no safety issues. Regulatory approval is required for the amendment.

Investment View: Retain Buy (Speculative) Valuation $1.40

PAR continues to expect to commence dosing in the phase 3 program in 1Q CY24. The company is funded though 1Q CY2024 and is yet to partner in a single region or indication. Non-dilutive funding from a regional partnering deals remains likely. Despite a promising outlook, the stock has been sold off as the sector remains out of favour with investors. Valuation is reduced to $1.40 (from $2.20) reflecting an increased discount rate in the DCF model and earnings adjustments to FY24/25.

Earnings Forecast

June Year End	FY23	FY24e	FY25e	FY26e
Revenues	0.0	0.0	35.7	70.8
EBITDA $m	-53.3	-52.5	12.4	36.2
NPAT (underlying) $m	-51.9	-52.0	12.9	36.7
NPAT (reported) $m	-51.9	-52.0	12.9	36.7
EPS underlying (cps)	-18.4	-17.9	3.9	11.1
EPS growth %	na	na	nm	1.8
PER (x)	nm	nm	15.3	5.4
FCF yield (%)	nm	nm	7%	23%
EV/EBITDA (x)	nm	nm	9.0	3.1
Dividend (cps)	-	-	-	-
Franking	0%	0%	0%	0%
Yield %	0.0%	0.0%	0.0%	0.0%
ROE %	na	na	6.4%	24.3%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Clinical Data Continues To Be Supportive

PARA_OA_008 – 12 month data

The company has previously reported interim data from PARA_OA_008. This exploratory study was designed to analyse the durable effect on osteo arthritis (OA) pain and function in addition to exploring the disease modify characteristics of the drug via a biomarker analysis. The primary endpoint - a change in one or more synovial fluid biomarkers associated with OA disease progression was achieved at Day 56 and were also present at day 168.

The company has now released the top line day 365 data for pain, function and stiffness (figure 1). There were approximately 20 patients in each arm. The key points were:

Figure 1 - Mean change in WOMAC pain (6w x 2 x 2mg/kg)

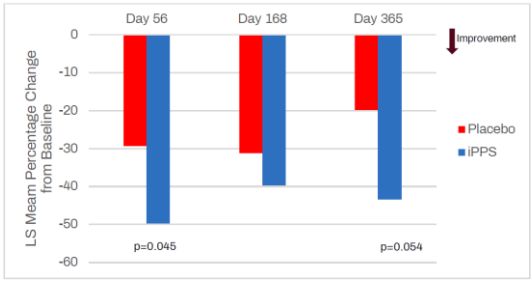


Figure 2: Adjusted LS mean % change in WOMAC pain from baseline at Day 56, 168 and 365 of participants treated with twice weekly iPPS versus placebo.

SOURCE: COMPANY DATA

Figure 2 - Patients with 30% of greater pain relief

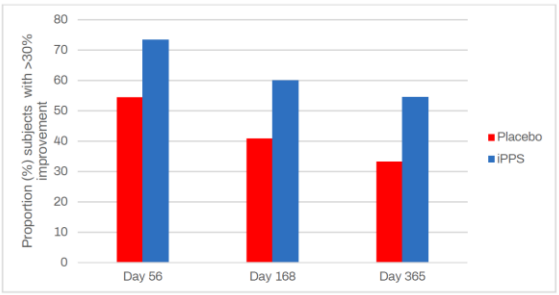


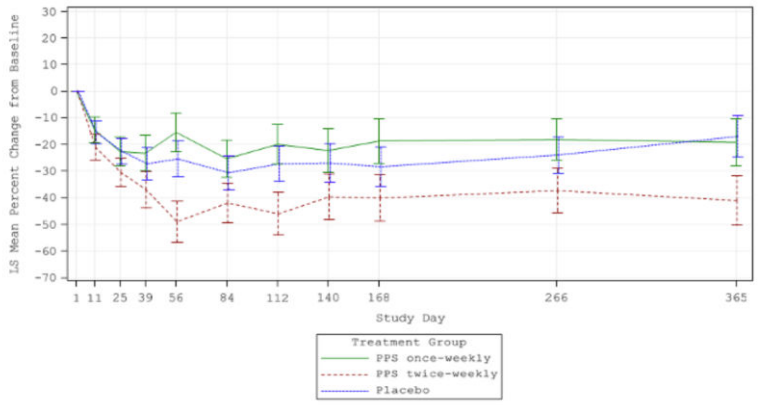
Figure 3: Proportion of participants treated with twice weekly iPPS reporting 30% or greater improvement in pain versus placebo.

SOURCE: COMPANY DATA

- In figure 1 – pain relief was sustained out to 12 months and consistently better than placebo;
- With so few patients we would not have expected to see a statistically significant result, despite this, the p value of 0.054 was within a whisker of achieving a statistically significant outcome. If similar effect size is displayed in the phase 3 trial across a much larger enrolment, it is likely the outcome would achieve a statistically significant result compared to placebo;
- Figure 2 demonstrates the proportion of patients with at least 30% reduction in chronic pain. At day 365 ~55% of patients continued to experience at least a 30% reduction in pain vs 33% on placebo;
- Patient assessed global impression of change at 12 months was statistically significant (p-0.005) for the twice weekly cohort compared to placebo; and
- Rescue medication (paracetamol, aspirin) was 5 x lower in the twice weekly treatment regimen than placebo

These outcomes also highlight the key risk in pain trials i.e. placebo effect. ~33% of patients on placebo continued to report very significant pain relief after 1 year. The placebo effect is also demonstrated in the broader analysis in figure 3 below.

Figure 3 - Overall WOMAC scores days 56, 168 and 365 across dosing regimens



SOURCE: COMPANY DATA

The key points in relation to figure 3:

- The 6 week twice weekly dosing at 2mg kg dose clearly produced the greatest level of improvement in pain function and stiffness at all points;
- At this dose, the effect size was at a maximum at day 56, before trailing off all the way out to day 365;
- The once weekly dosing is clearly under treating patients and under performed placebo;
- The gap between placebo (saline) and the twice weekly dose of iPPS was sustained at all points through the 12 months study and was at its widest at 12 months.

PARA_OA_002

The global phase 3 clinical trial is now operating in seven countries following regulatory and ethics approvals from the key regulatory agencies in Europe, the United Kingdom (UK), and Canada during FY2023.

All patients have now been dosed at one of the 3 dosing regimes selected for stage 1 of this two stage trial. The doses were:

- 1.5 mg/kg calculated for ideal body weight (IBW) PPS twice weekly;
- 2 mg/kg IBW PPS once weekly + placebo once weekly;
- 100/150/180 mg PPS if ≤ 65 kg/ ≥ 65 kg and ≤ 90kg/ > 90kg IBW+ placebo once weekly; or
- placebo twice weekly.

These doses were selected in order to determine the lowest efficacious dose and also in response to some concern regarding adrenal insufficiency (toxicity) in earlier pre-clinical work at higher dose.

The 12 month OA_008 data released today demonstrated that the lower dose (once weekly) did not show any material difference in efficacy vs placebo.

Subsequently, the company requested the Data Monitoring Committee responsible for PAR_OA_002 to perform an interim efficacy analysis at day 56 of each of the treatment arms in OA_002 as detailed above. It found (not surprisingly) that neither of the dose regimes (including the twice weekly at 1.5mg/kg) showed efficacy vs placebo.

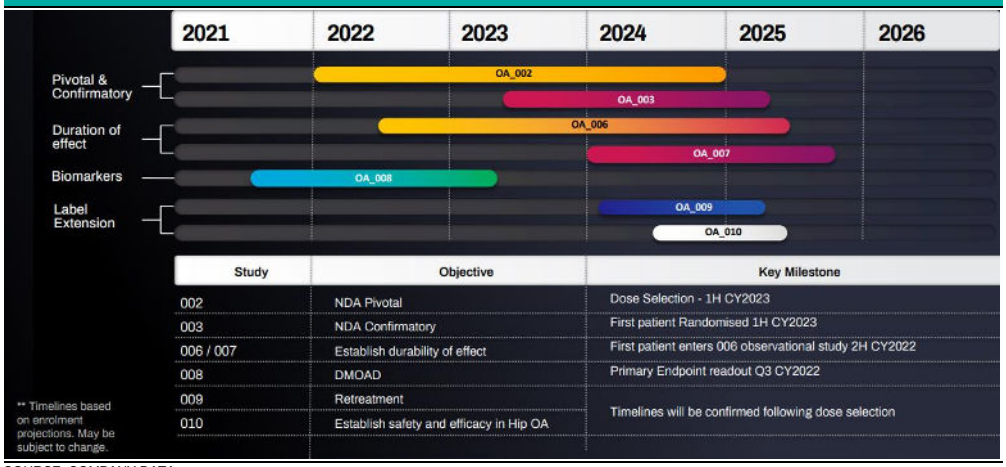
As a result the OA program is now expected to focus on the 2mg/twice weekly regimen.

The twice weekly 2mg/kg dose is not included as one of the options for final dose in PARA_OA_002. In fact, it was excluded in order to determine the lowest efficacious dose. The phase 3 clinical program will now require an amendment.

Consequently:

- The 6 week, twice weekly dose at 2mg/kg is the only viable dose to take forward to approval studies (i.e. the final dose);
- The company does not believe it will be required to perform additional toxicity or efficacy studies at the final dose as all relevant clinical and pre-clinical tox data at the final dose is available. This is now a crucial point and the company will be reliant on the data from previous studies, the SAS program and pre clinical data to satisfy regulators on the issue of safety;
- The company will discuss the change of protocol to include the twice weekly 2mg/kg dose with regulators in Europe and the US before commencing enrolment of either of the phase 3 trials; and
- PAR continues to expect to commence enrolment of the phase 2 programs 1QCY24. iPPS has fast track designation in the US and Europe and this will accelerate access to these important discussions.

Figure 4 - Clinical Trial Program



SOURCE: COMPANY DATA

MPS VI

Enrolment of the Phase 2 trial in MPS VI is completed. This 24 week randomised study compares to placebo evaluating safety and tolerability. Secondary endpoints include iPPS effects on pain, function, and glycosaminoglycan (GAG) levels at 6, 12, and 24 weeks. Headline data due in 4Q23.

The earlier trial in MPS I met primary endpoints of safety and tolerability and reported meaningful improvements in activities of daily living and overall improvement in quality of life.

OUTLOOK

The major data releases over the next 12 months include:

- 6 month imaging data from PAR_OA_008;
- Type D meeting with the FDA to discuss dose selection for the final dose;
- Headline data from MPS IV; and
- Publication of peer reviewed data sets from PAR_OA_008; and
- Finalisation of the dose for the phase 3 and confirmatory studies.

PARTNERING

PAR is yet to partner iPPS in either OA or MPS in any jurisdiction. As the drug is now in later stage development, the company may consider a non-dilutive funding deal in China.

Previously published meta analysis data regarding the prevalence of OA in China indicated 19.1% of females and 10.9% of males have symptomatic OA. Amongst older generations the rate increased to 42% for men aged 60-69 and 51% for women in the same age group[1]. Approximately 9% of the Chinese population is aged 64 years and older representing ~130m people, hence we can safely say the potential patient population with symptomatic OA is in the tens of millions.

The efficacy of iPPS is yet to be studied in a Chinese population, however, there is no reason to believe it would be clinically different to other countries.

Benchmark transactions are always difficult to assess and there are no near comparisons in the OA indication. In the context of Australian companies in China, in November 2020 TLX entered into a strategic commercial partnership with Grand Pharma for the Chinese market for TLX's portfolio of molecularly targeted radiation products. The deal covered Therapeutics for prostate cancer and renal cancer, none of which were approved at the time.

In relation to Therapeutic products only, material terms included a deal value of US$260m comprising US$25m upfront with the remainder attached to regulatory and commercial milestones. In addition Grand Pharma made a one time equity investment in TLX for US$25m (which it sold later at a considerably higher price).

China is a significantly lower price market for medical drugs and devices, nevertheless, the OA market in China dwarfs the radiopharmaceuticals market in patient numbers.

We suggest an upfront of US$25m is minimum value for any deal for iPPS in China, along with extensive commercial and development milestones.

Outside of China, there is also potential for a deal in MPS based on the phase 2 trial data. MPS is an ultra orphan indication and in relative terms is likely to attract a modest deal value. The company is in active discussion with potential regional partners.

Funding

Cash burn for the June quarter was ~$17m relative to $56.3m in cash at 30 June 2023. The burn rate is expected to decline in the short term as enrolment stage 1 of PAR_OA_002 is complete.

Current cash reserves fund the company to approximately 31 March 2024 with headline data from the phase 3 clinical trials due approximately 1 year there-after (our best estimated is 1H CY25).

Earnings Changes

Figure 5 - Summary of earnings changes

	2024			2025		
	New	Old	% change	New	Old	% change
Revenues	0.0	64.5	na	35.7	62.2	-43%
EBITDA	-52.5	12.2	-123%	12.4	40.0	-69%
NPAT	-52.0	12.7	-124%	12.9	40.5	-68%
EPS	-17.9	4.4	-125%	3.9	13.9	-72%

SOURCE: BELL POTTER SECURITIES ESTIMATES

The $35.7m in forecast revenue in FY25 relates to an upfront milestone payment for OA in the US, albeit this is substantially risk adjusted. The timing of any such transaction is

[1] Danhui Li et al The Prevalence of symptomatic knee osteoarthritis in relation to age, sex, area, region and body mass index in China: A systematic review and meta analysis.

assumed to occur after the announcement of headline data from the phase 3 program which we do not expect until 1H CY25. The company is likely to require funding before then whether through a non dilutive funding deal or a capital raise or both.

The model had previously assumed an upfront component from a US license transaction in FY24 for OA. This is now unlikely. We firmly believe the company will partner iPPS at some point and the later this happens the better as the deal value is maximised with mature data.

We include a $25m capital raise in FY25 albeit the need for further capital from shareholders depends largely on the outcomes of a non-dilutive funding transactions, if any. If there is no non dilutive funding, it is likely the company would have to raise a significantly higher sum from shareholders.

Given the outstanding potential of iPPS as demonstrated by clinical data to the point, we expect keen interest from potential partners in China. The model does not include an upfront from a deal in China at this time.

PAR also intends to apply for a provisional approval for iPPS with the TGA in Australia based on currently available data. The earliest possible approval is mid CY2025. The provisional approval would be subject to confirmatory phase 3 data.

Valuation

Despite a promising outlook, the stock has been sold off as the biotechnology sector remains out of favour with institutional investors.

The risk appetite amongst investors does appear to have softened as the pointy end of the clinical program looms. Valuation is reduced to $1.40 (from $2.20) reflecting an increased discount rate in the DCF model, delays to milestone income from a license deal and elevated risk weighting for future revenue generation.

We continue to believe the clinical data is supportive of a marketing approval for iPPS in knee OA. In our view the stock remains well over sold and therefore we retain our Buy Speculative rating.

Paradigm Biopharmaceuticals

Paradigm Biopharmaceuticals is an Australia biotechnology company focused on repurposing Pentosan Polysulfate Sodium (PPS) for the treatment of Osteoarthritis (OA) in the knee. If approved the drug will have the brand name Zilosul.

The global market for a safe, effective treatment that provides superior patient outcomes compared to the standard of care is a multiple blockbuster. The recently completed phase II study produced some highly encouraging results that are worthy of further clinical trials.

In the US along the incidence of moderate to severe osteoarthritis is estimated at 30m persons. The pricing of the drug will ultimately be determined by the economic benefit associated with its use as well as the cost of other therapies. The conservative estimate is US$2,500 per year which places the addressable market in the tens of billions of US$.

Within the FDA's Centre for Drug Evaluation and Research (CDER), it is the office of Neuroscience – Division of Anesthesiology, Addiction Medicine, and Pain Medicine that is (DAAP) that is responsible the review of iPPS.

PROGRESS IN THE CLINIC

December 2018 - PAR announced headline results from its phase 2b randomised, double blind, placebo controlled multicentre trial, investigating subjects with Osteoarthritis and concurrent Bone Marrow Edema (BME) lesions (n=112). The trial met the clinical endpoint of change in Knee Injury and Osteoarthritis Outcome Score (KOOS) pain achieving both clinically meaningful and statistically significant results between placebo and PPS.

The headline results were followed up with strong signals of efficacy in the secondary endpoints (including KOOS function). This phase II trial was conducted at 6 sites in Australia.

PATHWAY TO APPROVAL

PARA_OA_002 is the first of the company's two phase 3 trials. Stage 1 is a dose selection whereby participants are randomised to receive one of three PPS dose regimens or placebo for 6 weeks. The primary objective of stage 1 will be to select the dose for use in stage 2 and Paradigm's subsequent confirmatory trial (PARA_OA_003).

In stage 2, participants will be randomised 1:1 to receive the selected PPS dose regimen or placebo for 6 weeks. The primary endpoints in the pivotal study are change from baseline at Day 56 in the standardised WOMAC® pain questionnaire with secondary outcomes to include change from baseline at multiple time points out to day 168 in WOMAC® pain and function, Patient Global Impression of Change (PGIC), and Quality of Life (QoL) assessments.

PAR_OA_002 is expected to enrol 700 participants in total. PARA_OA_003 is expected to enrol 700 patients.

ADJACENT INDICATIONS

The second indication for PPS is mucopolysaccharidoses (MPS), a group of inherited lysosomal storage disorders. A key unmet medical need in this class of inherited disease is the lack of treatment of joint pain and dysfunction akin to osteoarthritis, hence the applicability of iPPS in treating these rare joint diseases. MPS is classified as an Orphan Indication/Designation in the US/EU and provides Paradigm the opportunity to serve a US$1.4bn p.a. market that is in desperate need of new cost-effective treatments.

KEY RISK AREAS

Regulatory Pathway - PAR is seeking registration for iPPS under the 505(b)2 regulatory pathway. The pathway is designed specifically for repurposed drugs including changes in

dose form, strength, route of administration, formulation, dosing regimen or indication. This proposed repurposing of PPS has some rare characteristics.

While the drug has been approved for years as an oral format and there is ample safety data, the proposed format, the dose and the indication (being OA) are all new.

There is also the issue of the opioid crisis. PPS is a non steroid, non opioid, non addictive substance that has been shown to have a significant impact of pain levels associated with OA. It may help to reduce the accidental deaths from opioid overdose.

PAR will present a comprehensive set of safety data from the recent Phase II trial together with data from subjects treated in the compassionate use program and two phase 3 trials, thus representing a safety set of nearly 1,700 subjects. The evidence of treatment will be established from two adequate and well controlled studies and further supported by the phases 2 data set.

Intellectual Property

The company has several patents over the formulation and dosing on iPPS for the treatment of OA. The validity of these patents is highly likely to be challenged at some point, especially if the drug is a commercial success.

The company has an exclusive supply contract with Bene Pharmaceuticals (Bene). We understand the exclusivity applies to human use only (excludes veterinary use). Bene holds the only drug Masterfile with the FDA to manufacture PPS. This supply contract represents a crucial piece of the company's value as it effectively prevents or delays the creation of generics.

We are not aware of the contractual conditions that may lead to a termination of this contract (if any).

We understand there are some other manufacturers of PPS, however, these products are not registered for human use and may not be referenced in any application for registration for human use. We understand the primary use of these products is veterinary.

Clinical Risk

The efficacy of iPPS has not been validated in a large, multicentre, randomised, controlled clinical trial. There is no guarantee that the results from earlier studies will be repeated in a larger phase III study.

Commercial Validation

Our valuation makes assumptions regarding selling price and volume in relation to future revenues from the sale of iPPS. In order for physicians to prescribe the drug and for payers to offer reimbursement, the clinical trials will need to demonstrate clinically significant improvement over the standard of care i.e. meaningful improvement in patient quality of life for pain reduction, side effect management and mobility amongst others. Early indicators based on the data from the phase II study are encouraging.

Revenue Forecast and Funding

Our financial forecast includes an assumption that the company completes an out license deal for iPPS in FY25. The nature of this transaction includes a large upfront payment followed by a series of development milestones. Transactions of this nature are commonplace in the biotechnology industry, however, the execution of such a transaction is dependent upon numerous factors including but not limited to the results of clinical trials, the company's funding position and demand from potential partners.

There is no guarantee that such a transaction will be executed and the terms of any such transaction may be different to the assumptions in the model.

Paradigm Biopharmaceuticals

as at 10 October 2023

Recommendation	Buy, Speculative
Price	$0.60
Valuation	$1.40

Table 1 - Financial summary

Profit & Loss (A$m)	FY22	FY23	FY24e	FY25e	FY26e
Year Ending June					
Risk adjusted revenues	**0.1**	**-**	**-**	**35.7**	**70.8**
COGS (Bene Royalty expense)	-	-	-	(1.8)	(3.5)
Gross profit	-0.1	0.0	0.0	33.9	67.2
GP margin	0%	na	0%	95%	95%
R&D incentive	8.7	7.0	11.0	7.0	-
Other expenses	-48.0	-60.3	-63.5	-28.5	-31.0
EBITDA	-39.4	-53.3	-52.5	12.4	36.2
Depreciation	-	-	-	-	-
Amortisation	-	-	-	-	-
EBIT	-39.4	-53.3	-52.5	12.4	36.2
Finance income	-	1.4	0.5	0.5	0.5
Pre tax profit	**-39.4**	**-51.9**	**-52.0**	**12.9**	**36.7**
Tax expense	-	-	-	-	-
NPAT- reported	-39.4	-51.9	-52.0	12.9	36.7

Cashflow (A$m)	FY22	FY23	FY24e	FY25e	FY26e
Gross cashflow	-32.2	-46.1	-52.5	12.4	43.0
Net interest	0.0	0.9	0.5	0.5	0.5
Tax paid	0.0	0.0	0.0	0.0	0.0
Operating cash flow	-32.2	-45.2	-52.0	12.9	43.5
Maintenance capex	0.0	0.0	0.0	0.0	0.0
Capitalised clinical trial spend	0.0	0.0	0.0	0.0	0.0
Free cash flow	-32.2	-45.2	-52.0	12.9	43.5
Business acquistions	0.0	0.0	0.0	0.0	0.0
Proceeds from issuance	0.1	62.2	0.0	24.0	0.0
Movement in debt	0.1	0.0	-0.1	0.0	0.0
Dividends paid	0.0	0.3	0.0	0.0	0.0
Change in cash held	(32.0)	17.3	(52.1)	36.9	43.5
Cash at beginning of period	71.0	39.7	56.3	4.2	41.1
Cash at year end	39.7	56.3	4.2	41.1	84.6

Balance Sheet (A$m)	FY22	FY23	FY24e	FY25e	FY26e
Cash	39.7	56.3	4.2	41.1	84.6
Receivables	6.7	6.8	6.8	6.8	-
Other current assets	0.8	0.7	0.7	0.7	0.7
Intangibles	3.0	3.0	3.0	3.0	3.0
Other	0.5	0.3	0.3	0.3	0.3
Total assets	50.7	67.1	14.9	51.8	88.6
Trade payables	7.1	12.2	12.2	12.2	12.2
Debt (leases)	0.6	0.3	0.2	0.2	0.2
Other provisions	0.7	0.9	0.9	0.9	0.9
Total Liabilities	8.4	13.4	13.2	13.2	13.2
Net Assets	42.3	53.7	1.7	38.6	75.3
Share capital	147.1	209.9	209.9	233.9	233.9
Retained earnings	(114.1)	(163.6)	(215.6)	(202.7)	(165.9)
Reserves	9.3	7.4	7.4	7.3	7.3
Shareholders Equity	42.3	53.7	1.7	38.6	75.3

Last sale 10/10/2023	0.60
Recommendation	Buy (Spec)
Issued Capital	280.5
Market Cap	168.3

Valuation Ratios (A$m)	FY22	FY23	FY24e	FY25e	FY26e
Reported EPS (cps)	-16.9	-18.4	-17.9	3.9	11.1
Normalised EPS (cps)	-16.9	-18.4	-17.9	3.9	11.1
EPS growth (%)	na	na	na	nm	184%
PE(x)	**nm**	**nm**	**nm**	**15.3**	**5.4**
EV/EBITDA (x)	nm	nm	nm	9.0	3.1
EV/EBIT (x)	nm	nm	nm	9.0	3.1
NTA (cps)	16.9	18.0	-0.5	11.1	22.5
P/NTA (x)	0.0	0.0	-1.3	0.1	0.0
Book Value (cps)	18.2	19.1	0.6	12.0	23.4
Price/Book (x)	0.0	0.0	1.0	0.1	0.0
DPS (cps)	-	-	-	-	-
Payout ratio %	0%	0%	0%	0%	0%
Dividend Yield %	0.0%	0.0%	0.0%	0.0%	0.0%
Franking %	0%	0%	0%	0%	0%
FCF yield %	nm	nm	nm	7%	23%
Net debt/Equity	0%	0%	0%	0%	0%
Net debt/Assets	0%	0%	0%	0%	0%
Gearing	net cash	net cash	net cash	net cash	net cash
Net debt/EBITDA (x)	n/a	n/a	n/a	n/a	n/a
Interest cover (x)	n/a	n/a	n/a	n/a	n/a

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

Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.

Such investments may carry an exceptionally high level of capital risk and volatility of returns.

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